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DESIGN STUDY - THERMOPROCESSED FOOD CONTAINERS INJECTION MOLDED HALF-SIZE STEAM-TRAY FOR STORAGE & SERVING OF PROCESSED FOODS

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The purpose of this program was to design, select, and evaluate plastic materials for an injection molded, half-size steamtable tray to be used for the storage, reheat, and serving of processed food items at government facilities.

In performance of this study, Springborn Laboratories, Inc. conducted a survey of plastic materials for use as a food tray based on literature stated properties, followed by a laboratory investigation of heat distortion temperature, and flexural modulus at elevated temperatures. Candidates include polysulfone, talc filled polypropylene, poly (4 methyl pentene-1), polyacetal, –

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20. ABSTRACT (cont'd)

talc filled Nylon 6/12, polycarbonate, and Nylon 12.

PVDC and polester-based cover films were also investigated.

A design was developed for the food tray along with production cost estimates for the tray based on the three most promising plastic materials, polycarbonate, polysulfone, and talc-filled polypropylene.

Finally, a prototype single-cavity mold was designed and fabricated and injection molding trials were conducted. Samples of trays in both 0.045- and 0.090-inch wall thickness were submitted to NARADCOM for evaluation of dimensional stability at elevated temperatures and food storage performance.

PREFACE

This study was conducted in response to the Military Service Requirement (MSR) titled Improved Subsistence Packaging Systems, USA 4–3. The MSR stated the need for improved quality and convenience of shelf-stable foods in the standard B ration, which provides the primary basis for hot meals in the field. The MSR also indicated that new and more efficient means will be needed for preparation and delivery of food in the field, particularly in active combat areas.

Natick Laboratories tests showed that foods hermetically sealed in rectangular containers of half steamtable size, approximately two inches in depth, can be heated and thermally processed in less time than cylindrical containers of equal capacity and can mean shelf-stable foods with improved quality. When made from polymeric materials, such containers may also serve where nonmetallic or nonmagnetic, and completely disposable materials are required. Initial tests with polymeric containers made by thermoforming lacked durability for rough handling and shipping. Injection molding, another method by which such containers can be produced, offered a plausible approach to strengthen the container.

The contract work covered by this report was performed under Project 1Y762724AH99, Food Technology, Task Area BC – Subsistence Technology. The Contract Project Officer was Joseph W. Szczeblowski.

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INTRODUCTION

This report will summarize work performed on the design and material requirements for an injection-molded, half-size steamtable tray to be used for the storage, reheat, and serving of processed food items at government facilities. This intended use imposes the following performance requirements:

1. Size and shape to be as specified for volume and interface with food-handling equipment;

2. FDA to approve food-contact service on all surfaces in contact with food;

3. Reliable hermetic seal and overall barrier properties to be sufficient to prevent spoilage and retain flavor during the storage period;

4. Strength and rigidity to be adequate to withstand handling, shipping, and storage;

5. Shape and seal to be retained under conditions required for sterilization;

6. Shape – and seal if required – to be retained under conditions required for reheat and serving;

7. Cost or performance effectiveness to be in comparison with alternate systems.

Alternate systems in current use and/or in test and development and their salient features are described in the following list.

1. **Number 10 can.** The can has many years of proven performance; technology well known and widespread; low cost; slow sterilization and reheat due to low ratio of surface area to volume; microwave reheat is not possible; separate steamtable serving tray is required.

2. **Steel, half-size steamtable can.** This can is now in test and development; technology for double seam seal at the corners not widely available; shape requires modification of standard sterilization equipment; faster sterilization and reheat than the No. 10 can due to higher surface area to volume ratio; microwave reheat not possible; no separate steamtable serving tray required.

3. **Retortable Pouch.** FDA approval was recently received on heat-seal coatings for aluminum foil; heat transfer and surface area to volume ratio should allow rapid sterilization and reheat. Nonrigid container with protection requirements for storage and handling; microwave reheat not possible; separate steamtable serving tray required.

4. **Thermoformed Plastic Tray.** Microwave reheat is possible; use of extruded sheet for thermoforming permits a sandwich construction such as an FDA approved, heat sealable surface backed with a barrier film and lower-cost shell; heat transfer not as good as metal tray; less rigid than molded tray;* possible requirement for a separate steamtable serving tray; higher cost than metal trays.

5. **Molded thermoplastic tray.** Microwave reheat is possible; heat transfer not as good as metal trays; material to satisfy all processing and performance requirements not currently available; sandwich construction difficult to product;* rigidity sufficient to serve as a steamtable serving tray; higher cost than metal trays.

If we assume that a thermoplastic raw material capable of meeting the process and performance requirements is available, the molded tray might have the following desirable characteristics: sufficient clarity to permit contents identification; visual indication of spoilage — color change or bulged heat seal film; lower overall energy use: reusable as a storage container — cover but no seal; possible recycle material or disposable as fuel.

DEVELOPMENT AND DESIGN STUDY

A. Material Review

Two categories of polymeric materials were investigated for the thermoprocessable food tray: rigid thermoplastics for the container itself, and plastic/foil laminates for use as hermetically sealed cover films.

The basic material requirements were:

1. The plastic must be sufficiently strong and rigid to resist deformation and breakage when the container is filled with food and is unsupported in the bottom. (Support is in the rim area only.)

2. The plastic must be impact resistant so as to resist breakage when the container is dropped.

3. The plastic must be able to withstand extremes of temperature, up to 260°F for 60 minutes, without distortion during commercial, pressurized water retort sterilization.

4. Both film and plastic must be FDA approved for contact with food.

5. The plastic must be capable of being formed in thin section by injection molding.

*Hermetic seal technology similar to pouch.

6. Both the film and container material must lend themselves to heat sealing in order to obtain a hermetic seal in the container.

7. Both film and container material must have sufficient barrier to oxygen and water vapor so as to prevent drying (escape of water) and oxidation and spoilage (uptake of oxygen) of the contents of the container during storage.

Review of Publications on Candidate Materials

The literature on candidate materials as reviewed particularly for materials' resistance to heat and their status as FDA approved-for-food contact. Principal elements of the review consisted of a study of published information on candidate materials, letters of inquiry to supplier companies, and discussions with the technical representatives of supplier companies.

The initial information received indicates that polysulfone might be the best first choice among heat-resistant materials that can be injection molded and that have FDA clearance. There appeared to be some likely candidates among materials that would have to be thermoformed into the tray shape, and thermoset materials, which are widely used for food contact but which do not have official FDA sanction. The most significant hindrance we found was that there were no FDA-sanctioned, high-temperature thermoplastics that are reinforced with glass fiber; this reinforcement of existing resins would permit consideration of several choice candidate materials for the subject tray.

Later investigations uncovered such a reinforcement that could be compounded into thermoplastics (no formal FDA approval required).

Information from the survey of candidate materials from published data and supplier contacts is summarized in Table 1. The table compares potential candidates from the criteria of flex modulus, izod impact, heat distortion temperature, cost is \$/lb approximate, and status with regard to FDA approval.

The 264 psi heat distortion temperature corresponds roughly to the design loading requirement, and is a rough predictor of load-bearing performance of the container at elevated temperatures.

Review of Literature on Oxygen and Water Permeability

To prevent drying and spoilage of the food stored over long periods of time in the plastic food trays, it is necessary that the materials of construction have good barrier properties. Table 2 lists, on a comparative basis, barrier properties of more common plastic materials.

A comparison of materials reveals that polyolefin polymers such as polypropylene (PP) and low density polyethylene (LDPE) have a comparatively good barrier to water while they are poor against oxygen. Traditional barrier materials such as Nylon 6, polyester (PET, polyethylene terephthalate) and the high acrylonitrile polymers (Nitriles) on the other hand, while much better barriers against oxygen, are only fair against water vapor. These data

Table 1

Plastic Materials for Food Tray:
Initial Screening List of Moldable Candidates

Material	Stiffness (Flex. mod.)	Impact Izod 1/8" ft lb	Heat Distortion Temp., °F 66 psi	Heat Distortion Temp., °F 264 psi	Cost (1) (Approx. $/lb)	FDA
Nylon 66	200,000	1.6	360	150	1.08	
Same with 30% glass	1,000,000	3.0	500	490		
Acetal homopolymer	410,000	1.2	315–338	230–255	.86	
Same with 20% glass	880,000	.8	345			
Acetal copolymer	375,000	1.3	316	230	.86	
Same with 25% glass	1,100,000	1.8	331	325		
Acrylic	425,000	.3		250	.57	
Same with % glass						
Impact acrylic	320,000	2.3		205		
Polycarbonate	340,000	12.0	275	265	1.08	
Same with 30% glass	1,200,000	2.5	310	295		
P.C./ABS alloy	380,000	10.5	238	220		
Noryl	360,000	5	280	265	.82	
Noryl with 20% glass	750,000	2.3	293	290		
PET						
PBT	340,000	1.2	310	130	.94	
PBT with % glass	1,200,000	1.6	420	415		
PPO		1.5 (1/4)		375		
High Density P.E.	150,000	2.0			.31	
Same with % glass						
Polypropylene	250,000	2.0	230	140	.26	
Same with 30% glass	800,000	1.6	310	300		
Same with 30% talc						
Cellulose propionate	180,000	2.7		173	.82	

(1) In 1977 dollars

Table 1

Plastic Materials for Food Tray:
Initial Screening List of Moldable Candidates (cont'd)

Material	Stiffness (Flex. mod.)	Impact Izod 1/8" ft lb	Heat Distortion Temp., °F 66 psi	Heat Distortion Temp., °F 264 psi	Cost (1) (Approx. $/lb)	FDA
TPX	200,000	.8				Yes
ABS	400,000	2–4		245	.43	
Same with 30% glass	1,100,000	1.4	230	220		
SAN		.45		220	.42	
Same with 30% glass	1,450,000	1.0	230	215		
K resin						
Same with % glass						
Polyvinyl chloride	500,000	8.0	185	170	.26	
Same with 15% glass	850,000	1.2	165	155		
Polysulfone	390,000	1.3	360	345	2.20	Yes
Same with 30% glass	1,200,000	1.8	389	365		
Polyaryl ether	300,000	8.0	320	300		
Same with % glass						
Polyarylsulfone	400,000	5.0		525		
Polyethersulfone	375,000	1.6		400		
Polyphenylene sulfide	600,000	.4		278	2.00	
Same with 40% glass	2,200,000	1.4		425		
Torlon						
PFA						
FEP	80,000	no break			6.40	
ETFE	240,000	no break	240	170	6.60	
Same with % glass	950,000	7.0		285		
Polyphenysulfone	330,000	12.0		400	15.00	
Melamine–dishware				400	.35	
Polyester, % glass				400		
Epoxy, % glass	2,000,000	.45		340–400		

(1) In 1977 dollars

Table 2

Basic Barrier Polymer Properties

	Permeability: Oxygen Engl.	Oxygen Metr. x 10^{-5}	Carbon dioxide Engl.	Carbon dioxide Metr. x 10^{-5}	Water vapor Engl.	Water vapor Metr. x 10^{-7}	Absorption Dipentene	Density S.G.
0% R.H.								
PVA	0.01	0.004	0.03	0.001	2,000	78,000	•	1.3
Cellophane	0.13	0.05	0.3	0.12	365	14,000	•	1.2
100% R.H.								
EVAL	0.1/0.3	0.04	0.3/0.9	0.12	0.2/0.3	8	•	0.9
Nitriles	1.0	0.4	3.0	1.2	5.0	200	1 –	1.1
PVDC	1.3	0.5	4.5	1.8	0.5	20	•	1.7
Epoxy	3.0	1.2	9.0	3.5	4.0	160	•	1.7
PVDF	4.5	1.8	15.0	5.8	1.0	39	•	1.8
Nylon 6	5.7	2.2	12.0	4.7	6.0	240	•	1.1
PET	7.0	2.7±	16.0	6.2±	3.0	120±	•	1.4
Phenoxy	7.0	2.7	15.0	3.8	4.5	180	•	1.4
PVC	10.0	3.9±	30.0	12.0±	2.[illegible]	100±	15	1.4
Acetal	12.0	4.7	35.0	13.6	13.0	500	•	1.4
PMMA	17.0	6.6	40.0	15.6	12.0	470	•	1.1
HDPE	110	43.0	300	117	0.5	.20	•	0.9
PP	150	58.0	450	175	0.5	20	•	0.9
PTFE	220	85.0	600	233	0.3	10	•	2.2
Polycarbonate	225	87.0	550	214	14.0	550	•	1.2
Polystyrene	415	162	2,000	780	5.0	190	•	1.0
LDPE	480	187	1,500	583	1.5	60	98	0.9
EVA	1,500	583	6,000	2,330	40.0	1,560	•	0.9

Oxygen + carbon dioxide English units – cc/mil/100 in^2/24 hrs/1 atm @ 73°F. Metric units – csc/cm/cm^2/24 hrs/1 atm @ 23°C. Water vapor English units – gms/mil/100 in^2/24 hrs @ 100°F. Metric units – gms/cm/cm^2/24 hrs @ 38°C. Absorption % loss of solvent stored one month @ 49°C: solvent as 0.1% concentration in water-alcohol mixture.

Source: Plastics World, November 1979, P.2

suggested a double layer approach for the container, which was pursued and is covered in section D, Prototype Tooling and Fabrication of this report.

Laboratory Evaluation of Candidate Materials

Container resins, heat-sealable cover films and barrier coatings were evaluated as follows:

Container Materials – Molding: Samples of the more promising candidates from the literature screening were procured from suppliers and were evaluated in the laboratory for injection molding characteristics and resistance to deformation under conditions of heat and stress.

The following materials were injection molded into 4" x 14" x .06" sheets for use in further evaluations:

Hercules PD491 – 40% Talc filled polypropylene – FDA approved for continuous food contact;

Hercules PD181 – 40% Calcium carbonate filled polypropylene – FDA approved for repetitive food contact;

G. E. Lexan RL4087–112–FDA approved grade, maximum hydrolytic stability;

G. E. Lexan 1500–112–FDA approved; in current use for baby nursers (polycarbonate);

Mitsui TPX RT–18–FDA approved (poly-4 methyl pentene);

Celanese Celcon M–25–FDA approved (acetal);

Union Carbide Polysulfone 1700–FDA approved.

Comments on FDA approval status are published in the "Food Chemical News Guide" for the above materials and additives appear in the Appendix of this report.

Molding was done using a Beloit 325 RS 25 injection molding machine. The molding conditions for each material were as follows:

Material	Front Zone t°F	Mold t°F	Injection Pressure – psi
PD491	415	125	9,000
PD181	415	125	9,000
Lexan RL 4087–112	610	250	19,000
Lexan 1500–112	620	250	19,000
RT–18	525	125	8,500
M–25	380	175	11,500
Polysulfone	640	275	20,000*

*Did not fill.

From the above data, it is obvious that Polysulfone was the most difficult material to mold followed by Laxan.

Container Materials – Heat Deflection: Food trays will be commercially sterilized at temperatures of at least 250°F (121°C). Therefore, one of the material requirements was sufficient rigidity at this temperature to insure shape retention. Flex modulus, as an indication of rigidity over the operating temperature range, was determined for the materials listed above and is given in Table 3.

Table 3

Flex Modules (PSI x 10^5) of Candidate Plastics

	73°F	150°F	200°F	250°F	300°F
Polysulfone Udel–1700	4.57	5.17	3.75	4.92	3.24
Polypropylene PD181	5.24	2.66	1.31	.867	.350
Polypropylene PD491	7.91	3.60	1.85	1.44	.664
TPX RT–18	2.31	1.12	.679	.657	.387
Celcon M25	4.38	2.91	1.35	1.17	.518
Nylon 612/Talc	2.80	1.13	.816	.726	.781
Polycarbonate 141–111	3.59	4.37	3.28	4.14	.771
Polycarbonate RL4087	3.59	4.42	3.18	3.96	1.50
Nylon 12 Amorphous	2.93	2.80	2.42	3.08	.394

Using 1.0 x 10^5 as an arbitrary target flex modulus at 250°F, the polysulfone, talc-filled polypropylene, Acetal, polycarbonates, and amorphous nylon (Amidel, Union Carbide) all retained sufficient rigidity to warrant further investigation. It is interesting to note the effectiveness of talc (PD491) vs. calcium carbonate (PD181) as a filler for polypropylene.

Glass Fiber Reinforced Resin: As a result of discussions with LNP Corp. and Owens-Corning Fiberglas, it was learned that Owens-Corning had available what they believed to be an FDA approvable, glass fiber/sizing system.

Data from Owens-Corning appear in Table 4. These data indicate that P284A glass used with polybutylene terephthalate (PBT) is equivalent to standard glass reinforcement in its effect on heat distortion temperature, although not as good for some other mechanical properties. The 407°F deflection temperature under load at 264 psi represents a significant increase from the 130°–140°F values normal for unreinforced PBT.

Neither LNP Corp. nor Owens-Corning had any information on results to be obtained by using P284A glass with polyethylene terephthalate (PET). Therefore, Springborn Laboratories procured a sample of Goodyear PET (VFR 5877-Cleartuf 72) compounded with 30% P284A glass from LNP Corp. for evaluation.

Preferred Container Resins: Based on the above survey of potential materials and combinations, the following appeared to be possible candidates:

1. **Polypropylene** – talc-filled resin would be required to improve stiffness and temperature resistance without loss of FDA approval. While PP is a poor oxygen barrier, it was felt that it might be satisfactory if evaluated in thick-wall configurations.

2. **Polypropylene liner** – with a molded barrier shell. Barrier resin shell candidates included polyesters – PET's modified for impact and thermal properties, and nitrile barrier resins such as Barex. Sufficient bond between layers and migration of acrylonitrile through the inner shell were concerns, however.

3. **Polyester liner** – with a molded reinforcing shell. Bottle resin PET's have FDA approval and good barrier properties. but low impact strength in the unoriented (molded) state, and poor thermal properties. A reinforced polyester shell would overcome these limitations with possible FDA problems.

4. **Polypropylene liner** – in a preformed shell. A talc-filled polypropylene tray could be molded into a preformed barrier film shell such as aluminum foil, polyester (mylar), PVDC (saran), or PVDF (Kynar) to give a rigid container with good barrier properties. In particular, a coated foil shell would give a rigid "retortable pouch" permeable only at the lip, and, if the foil were strippable, a container that could be opened and heated by microwave.

Table 4

P–284A Fiber Glass Performance in Various Polymers

	Tensile	Flex		Izod		DTUL	
	Strength (psi x 10^3)	Strength (psi x 10^3)	Modulus (psi x 10^6)	Notched (ft–lb/in)	Unnotched (ft–lb/in)	@264 psi (°F)	Glass (%)
Nylon 6/6							
CONTROL	24.4	39.4	1.33	2.21	16.4	496	29.7
P284A	23.3	36.7	1.31	1.92	16.1	498	31.1
PPO (Modified)							
CONTROL	14.3	23.2	1.57	1.47	4.12	—	31.0
P284A	13.7	22.3	1.44	1.33	4.17	—	28.7
Polycarbonate							
CONTROL	15.6	27.4	0.99	2.13	9.98	—	21.5
P284A	13.4	21.0	1.01	1.90	6.17	—	19.8
CONTROL	9.4	17.4	0.67	1.26	29.30	—	9.9
P284A	10.9	19.4	0.65	1.08	8.30	—	10.4
PBT							
CONTROL	17.4	27.5	1.30	2.08	16.7	406	29.0
P284A	14.8	23.7	1.30	1.54	12.0	407	29.7
ACETAL							
CONTROL	8.8	15.8	1.09	1.03	5.81	318	24.9
P284A	9.8	17.2	1.15	0.92	5.40	320	24.8

Source: Richard P. Wood, Thomas A. Cookley, and Robert A. Schweizer. "Glass Fibers in Thermoplastics – A Study of Their Applicability," Owens–Corning Technical Center, Granville, Ohio, April 1978.

Heat-Sealable Barrier Films: Cover film for the container as well as barrier films for use in a dual-layer molded container were procured as follows:

1. **PVDC film laminate:** Sample rolls of Saran and Saranex films (Dow Chemical) were procured for use in a dual layer molded container. Based on discussions with the supplier, it was anticipated that problems would occur in achieving adhesion of the Saran to the container and in shrinkage. The most promising candidate appeared to be laminate of polyethylene/saran/EVA (Saranex X02004.23) where the EVA would be expected to provide adhesion to the molded tray;

2. Polyester and polyester film designed for "boil-in-bag" use (3M Company) for use as a cover film;

3. Polycarbonate (Lexan) coated foil used for bandage packaging application (General Electric);

4. Retortable pouch heat-seal foil designed for evaluation as a cover film for use with polypropylene molded trays (Continental Diversified Industries).

Barrier Coatings for the Container: One approach to providing a good, oxygen-impermeable barrier on a polyester or polyolefin container would be to coat from solution with a resin, such as a polyvinylidene chloride copolymer or a high acrylonitrile polymer. Dow Chemical was contacted with regards to Saran (PVDC) solutions and dispersions for use in coating. They felt that adhesion to polyester was possible, but that good adhesion to polypropylene was unlikely. Samples were provided.

Preliminary trials were made on coating (dip or brush process) saran on trays as a post-molding operation. An 18% solids solution of Saran Resin F239 was prepared in a 65/35 THE/Toluene mixture and applied to a PET tray. Thickness measurements indicated a 0.001-in coating with good adhesion and appearance.

B. Preliminary Design

Preliminary designs for trays, covers and methods of sealing were reviewed; comparisons were made with commercial types of box/cover combinations to assess types of seals and reclosures that might be used. The prime direction of effort was for a tray with a strong, channel-shaped edge, which would accept and hold a snap-fit cover for reclosure purposes. The hermetic seal would be gained by an initial heat seal of the cover or auxiliary membrane, or by a sealed assembly which can be opened — any of these configurations would then be capable of reclosure with loss of hermetic seal after the initial seal was broken.

A Comparison of Commercial Trays

Sources were sought for trays of approximately the size of interest, fabricated by injection molding. Trays were then procured and used to evaluate rigidity and ability to perform under

the requirements of the program, in particular the ability to resist the required temperatures. In addition, these trays were used as a guide to development of an optimum design for the NARADCOM tray.

Injection-molded polysulfone trays nominally 10" x 12" x 2–1/2" deep were obtained from two sources; information on the pans and covers is:

	Cambro	Rubbermaid
Overall tray size, in	10–3/8 x 12–5/8 x 2–1/2	10–3/8 x 12–3/4 x 2–5/8
Actual tray size, in	9 x 11–3/8 x 2–3/8	9 x 11–1/8 x 2–1/2
Tray capacity, fl oz	108	112
Weight of tray, g	314	419
Weight of cover, g	286	296.5
Tray thickness, in	~ .080 – .085	~ .095 – .105
Cover thickness, in	~ .090 – .096	.100

These trays were tested by exposure to the dry heat and internal pressure design requirements as shown in the following photographs, Figures 1 and 2. The tests indicated that, dependent on proper design, a molded polysulfone tray will meet these requirements. Test data are given in Table 5.

As a further test of container geometry, the Cambro tray described previously was given a convex (upward – .200 max) bottom and subjected to the 325°F, 10 lb load, test condition. Deflection measurements were as follows:

Time (min)		Deflection (0.001's)
0	Empty – cold	0
0	Loaded – cold	20
5	325°F	–15
10	325°F	2
15	325°F	11
20	325°F	16
25	325°F	19
30	325°F	22
40	325°F	25
50	325°F	27
60	325°F	34
80	325°F	46
100	325°F	67

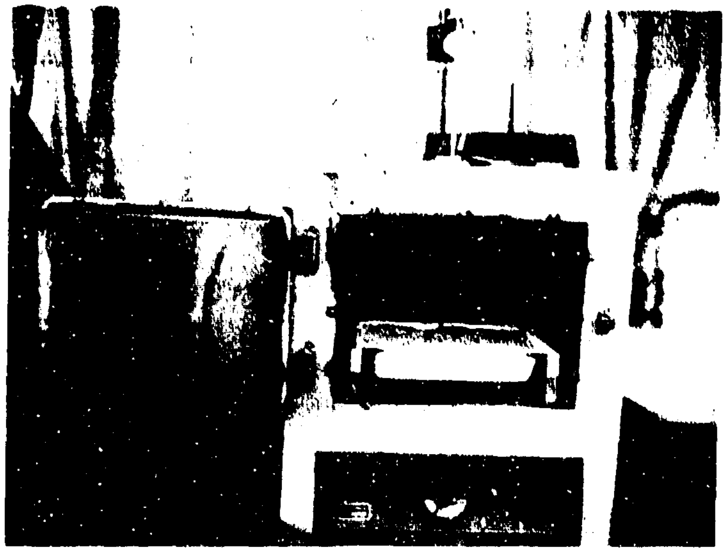

Figure 1. Deflection under load at 325°F

Figure 2. Deflection at 5 psi internal

Table 5

Deflection Versus Temperature for Commercial Trays
(Inches x 10^{-3} at –°F Under 10 lbs Distributed Load)

Time (min)		Rubbermaid A Temperature Raised Sequentially 200°	250°	300°	325°	350°	Rubbermaid B Single Test 325°	Cambro Single Test 325°	
0	Empty	0	0	0	0	0	0	0	
0	Loaded	10	4	9	–20(1)	–13(1)	8	55	0(2)
5			13	21	–9	5	20	59	4
10				32	9	24	39	76	21
15				39	16	34	51	90	35
20		30	28	46	22	40	58	99	44
25				48	29	45	68	109	52
30				50	32	51	69	113	59
40		38	31	54	37	63	77	128	73
50					40		85	139	84
60		39	31	60	43	99	92	154	99
70						149			
80		39	31	65	51	215	107	184	129
85						244			
90						269			
95						304			
100		39	31	69	63	334	122	211	156

Notes: (1) gage setting probably changed during loading
(2) deflection with time from preload value

Deflection (.001's) at 75° F – 5 psi internal

Rubbermaid	100	
Cambro	>68	– Air shut off before 5 psi was attained

The effective of the convex bottom can be seen by comparison of this data with the data for the flat bottom test (Table 5).

In considering the various design options, of very special interest is a decision on the shape of the bottom of the pan as to whether it can be flat (and at what thickness), whether it should be convexed upwardly (similar to the Rubbermaid design) or whether it should be flat and ribbed. The convex design gave good performance under test as described above but would require higher cost tooling when compared to a flat-ribbed configuration.

Hermetic Seal Design

Requirements for the hermetic seal membrane were an ability to heat seal (preferred assembly method) to the molded tray, retention of seal during process and storage conditions, FDA approval for long-term food contact, ease of removal, and barrier properties. We understand that FDA approval has been granted to "coated" foil heat seal pouches from Reynolds and Continental and hoped that the same or similar systems would work on a molded tray. The area of the membrane represents almost 40% of the area of the sealed container, and therefore contributes significantly to barrier characteristics. Coated foil was an obvious choice for this reason – probably in the 0.010-in range for strength – and also as a heat conductor for heat sealing. If microwave heating considerations become important, coated Mylar (polyester film) could be substituted for the foil with some loss in barrier properties. Either composite will permit removal by cutting with a sharp knife, or puncture to relieve pressure during reheat.

A number of design sketches of closure mechanisms were prepared to explore the means of accomplishing both the initial hermetic seal and the reclosure of the cover. It appeared that the latter should be done by using a latch configuration in the central areas of the edge overhangs of the cover. These can be sprung readily to open the cover. Representative sketches are shown in Figure 3.

Design planning for the hermetic seal and the temporary reclosure of the pan was as follows. The hermetic seal would preferably be accomplished by a fusion seal which would:

1. be controllable to be reliable and yet break open readily

2. or be firmly sealed in a section outside of the reclosure mechanism and outside of a planned opening segment. In this concept the heremetic weld is never broken, but the package opening and reclosure occurs inside of the weld perimeter.

Other seal mechanisms not based on true fusion of the container material but which were considered are:

1. A soft gasket entity held between the pan and cover; similar gasket seals are now used in plastic five-gallon pails that hold food.

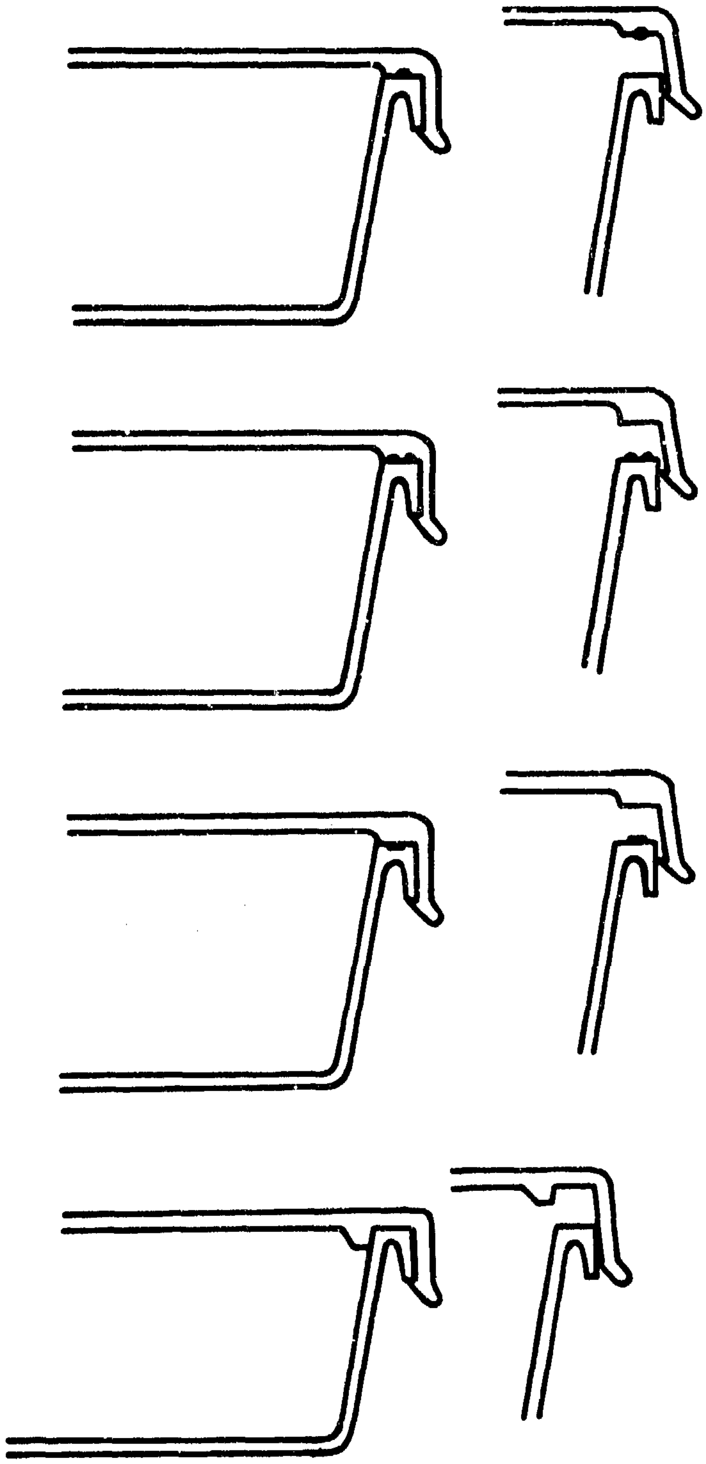

Figure 3. Closure design sketches

2. A poured-in-place gasket to accomplish the seal, gaskets of this type are used in home-canning jar covers and also to line the covers of beer and soft-drink bottle caps.

3. A hot-melt, adhesive-type gasket which "sticks" the pan and cover together and holds firmly with the help of the reclosure mechanism. After being peeled open, the hot melt surface remains in place and can serve as a good reclosure gasket. This concept, along with variations of 2., offers the additional safeguard of weakening when exposed to high temperatures, thus precluding a bursting of the package if it were put into the heating chamber without being opened.

Drawings ND–AI–D and ND–A2–D show concepts for a molded tray.

C. Design Study

After review of a variety of design options, a three-component tray design concept was developed as shown on Dwg. ND–A4–D, Appendix B. In this concept, the tray is molded from a material capable of meeting operational requirements, and the hermetic seal obtained through a heat-seal, membrane type cover. The snap-on lid is molded from the same material as the tray, or, because it does not have to go through the sterilization or reheat cycles, could be made from a less expensive material.

Requirements

The goals of the design study phase of the contract are drawings, specifications, and material selection for an injection-molded multipurpose container for food storage and service. It is intended that the container would be filled with prepared food at a processing facility (packing plant-commercial or government), hermetically heat sealed, and sterilized – liquid medium under balanced pressure at temperatures up to 127°C (260°F) determined by the type of food contained. After sterilization, filled containers would be shipped – commercial bulk pack, unrefrigerated – and stored prior to reheat and use with a shelf-life goal of two years at 21°C (20°F) for flavor retention. Alternative storage conditions and shelf life goals are 38°C (100°F) for six months. At the time of use, the container would be reheated either by microwave oven, circulating hot air oven, steamtable exposure, or immersion in a water bath at 88°C (190°F). The hermetic seal would be broken and the foil removed prior to heating by methods other than water bath immersion. Following reheat, the container would be maintained at serving temperature on a steamtable or transported (covered) to another serving location. It is not intended that the container be recycled, although field reuse would be probable.

Drawings and Specifications

The proposed design for a three-part container – tray, heat seal film, and snap on cover – is shown on Dwg. ND–A4–D. The tray is a one-piece molding designed to fit within one-half of a nominal 304 mm x 508 mm (12" x 20") steamtable opening and to have a capacity of 3.1 ± 10% (105 fl oz). The tray has an external horizontal flange to cover the opening, and prevent dropping through, plus a perimeter ring seat to allow for flat seating in spite

of table opening edge irregularities. The horizontal flange is stiffened by its tee configuration with the lower arm of the tee forming the ring seat, and the upper arm the cover close lip. Tapered (5°) sides and an internal step permit nesting and "no lock" separation. A concave bottom surface has been used for rigidity and resistance to internal pressure. Material thickness is a nominal 2.3 mm (0.090 in) giving an approximate molding volume of 337 cc (20.57 in) and a weight in the 400 g (0.88 lb) range dependent on material specific gravity. The overall dimension of a single tray are 260 mm x 322.5 m x 59.55 mm (10.235" x 12.695" x 2.34"). Trays will nest with an incremental addition of 10.0 mm (0.394 in) per tray. Thus a package of 50 empty nested trays would have outside dimensions of 260 mm x 322.5 mm x 549.55 mm (10.235" x 12.695" x 21.64") and a net weight of 20 kg.

Material Selection

No final material selection has been made for the molded tray, since all service requirements described above cannot be met by any material now available. Possible combinations of materials are discussed under D, which follows. The FDA approved polypropylene would be the material of choice for the snap-on lid.

Production Cost Estimates for the Tray

The cost estimates given in Table 6 show the range covered by the materials surveyed. Estimates were prepared based on the use of a 1500-ton injection molding machine as the largest capacity machine readily available, as well as the minimum size required for a single cavity tray mold in polycarbonate or polysulfone. Part costs, therefore, reflect both differences in raw material costs, and the larger number of cavities that can be used for the polypropylene tray. The annual capacities per machine are based on 6,000 operating hours.

D. Prototype Tooling and Fabrication

The scope of this portion of the effort involved design of a mold, fabrication of the tooling, and trial molding of trays from representative candidate materials. The purpose was to provide trays in sufficient number and of a convenient size to permit NARADCOM to conduct food storage tests.

Need for Food Storage Tests

Information obtained on the potential problems of long-term food storage in single material containers, with oxygen and water vapor permeabilities much higher than those obtainable with barrier film laminate construction, indicated a need to obtain actual experience data. For this reason, Springborn Laboratories proposed an intermediate program as a modification to Phase I to determine the feasibility of food storage in molded trays using currently available materials. Under this program, we designed and built a single cavity injection mold for a 5" x 6" (1/4 size) tray essentially as shown on Dwg. ND–A5–E. The wall thickness was in the 0.090-in range to duplicate the anticipated wall thickness of the full-sized, half steamtable tray to permit valid food storage time comparisons.

Table 6

Cost and output comparisons for polypropylene, polycarbonate, and polysulfone food tray sets

Manufacturing cost per set, with polyethylene cover,[1] in 1977 dollars (costs with tooling amortized are shown in parenthesis)

Quantity	Polypropylene[2] tray	Polycarbonate[3] tray	Polysulfone[3] tray
100M	$0.879 (1.329)	$2.881 (3.171)	$4.686 (4.976)
200M	.862 (1.087)	2.840 (2.985)	4.642 (4.787)
600M	.860 (0.937)		
1,200M	.852 (0.889)		

Notes:

[1] Polyethylene cover molded in 1,500-ton press at 4.5 tons per square inch using a 4 cavity, 2 on 2 stack mold configuration capable of an annual output of 1,470M units.

[2] Polypropylene tray molded in 1,500-ton press at 4.5 tons per square inch using a 4 cavity, 2 on 2 stack mold configuration capable of an annual output of 1,224M units.

[3] Polycarbonate and polysulfone trays molded in 1,500-ton press at 9 tons per square inch using a single cavity sprue gated mold capable of an annual output of 204M units.

The mold was then used at Springborn Laboratories to produce containers for actual food storage evaluation trials at Natick Laboratories. We molded containers from candidate materials — primarily those already under discussion above for the food tray, and, in the process evaluated each material for processing characteristics to permit more realistic production tooling and cost estimates. We also procured heat seal foil/film suitable for each tray material (if available), and developed the heat seal tooling and techniques required to produce sealed containers.

Mold Design and Fabrication

In accordance with Mod. p00004, a single cavity injection mold for a 5" x 6–1/2" x 1.2" tray was constructed per Dwgs. ND–A5–E through ND–A14–A. The mold was built by Peerless Tool and Machine in Enfield, CT. The interchangeable aluminum core and cavity inserts permitted the evaluation of single material trays with a wall thickness of 0.090-in. In operation, an 0.090-in wall tray was molded using the "shrink cavity insert: ND–A12–D with the "full wall core" ND–A11–D, and an 0.045-in wall tray was molded on the "half wall cavity" ND–A8–D with the "half wall core" ND–A9–D. This 0.045-in wall tray could then be placed in the ND–A11–D/ND–A12–D combination and a 2nd/0.045-in layer molded on the inside surface.

The ND–A11–D/ND–A12–D core/cavity set was also used to mold into a preformed barrier film shell.

Heat Seal Tooling

FMC was contacted for specifications and cost estimates on heat seal tooling to fit the Laboratory Heat Sealer — Model 1000–4 at Natick. FMC forwarded drawings and an estimate to cover the cost of a set of heat seal dies.

Heat seal platens for the 5" x 6" tray were ordered from Peerless Tool and Machine Company per Springborn Laboratories drawing ND–A15–D and ND–A16–D (FMC Dwgs. 5018996 and 5130698, modified) for use with the FMC 1000–4 laboratory heat sealer.

Trial Molding Runs

Talc Filled Polypropylene Trays: The 5" x 6" mold was run in a Beloit 325–RS 25 screw injection molding machine using Hercules PD491–FDA approved talc-filled polypropylene as the material for evaluation. Cycles for the 0.045-in and 0.090-in cavity sets were as follows:

		0.045-in	0.090-in
Temperatures:	Rear Zone	380°F	380°F
	Center	400°F	400°F
	Front	440°F	440°F
	Nozzle	440°F	440°F
	Melt	440°F	430°F
Times:	Inject	2 sec.	2 sec.
	Hold	6 sec.	10 sec.
	Closed	25 sec.	30 sec.
Pressures:	Inject	10000 psi	8000 psi
	Hold	6000 psi	6000 psi
	Clamp	225 tons	225 tons
	Back	75 psi	75 psi
Mold Temperature:		130°F	125°F
Shot Weight:		53.7 g	98.3 g

Molding of PET Trays

Trays measuring 5" x 6" x 0.09" were successfully molded from Goodyear VFR 5878 (Cleartuf 104), a PET similar to that used for soft drink bottles but with a higher intrinsic viscosity — 1.04 vs 0.72. The following cycle was used.

		0.090-in.
Temperature:	Rear Zone	525°F
	Center	535°F
	Front	560°F
	Nozzle	560°F
	Melt	565°F
Cycle Times:	Inject	4 seconds
	Hold	12 seconds
	Closed	35 seconds
Pressures:	Inject	12500 psi
	Hold	8000 psi
	Clamp	15000 psi
	Back	75 psi (gauge)
Mold Temperature:		150°F
Part Weight:		105 g

Tray as molded were amorphuous and unoriented — semi-transparent and tough. Barrier properties would be improved by crystallization, but 266°F is a minimum crystallization temperature — not practical for injection molding since the parts stick at mold temperatures above 180°F. An attempt will be made at a later date to crystallize a part by cycling the mold as well as evaluating a lower intrinsic viscosity resin (Cleartuf 72). Trays molded from Cleartuf 104 had a heat distortion temperature in the 190°F range while the PD491 polypropylene trays discussed above retained shape in the 250°F dry oven.

Molding of Glass-Filled PET Trays

Trays measuring 5" x 6" x 0.045" were molded from both Goodyear VFR 5877 (Cleartuf bottle resin) and the same material filled at the 30% level with Owens Corning P284A fiberglass. The P284A glass is the potential FDA grade discussed under Laboratory Evaluation of Candidate Materials of this report. Compounding was done by LNP Corporation of Malvern, PA under their experimental designation PDX 78732.

Molding cycles used were as follows:

		VFR 5877	PDX 78732
Temperature:	Rear Zone	520°F	520°F
	Middle	540°F	540°F
	Front	560°F	570°F
	Nozzle	560°F	570°F
	Melt	—	550°F
Pressures:	Inject	15000 psi	18500 psi
	Hold	5500 psi	5000 psi
	Clamp	—	—
	Back	75 lbs	75 lbs
Times:	Inject	2.5 sec	0.7 sec
	Hold	5 sec	3 sec
	Closed	40 sec	40 sec
Mold Temperature:		125°F	100°F

Trays molded from both materials were amorphous (semi-transparent). A sample tray molded from PDX 78732 was oven cycled at 250°F with almost no evidence of distortion, but with a change of appearance from semi-transparent to opaque probably an indication of crystallization. This would indicate the possibility of crystallization after molding, perhaps during sterilization with a resulting decrease in permeability values.

Molding of Trays Using a Double-Shot Technique

Trays measuring 5" x 6" x 0.045" were molded from PDX78732 using the cycles detailed in above. These trays were placed in the 0.090-in cavity set (modified for shrinkage allowance) and held in place with vacuum. Polypropylene (PD491) was injected into the cavity to form a molded in-place liner using the following cycle:

		PD491
Temperature:	Rear Zone	380°F
	Middle Zone	410°F
	Front Zone	440°F
	Nozzle	440°F
Pressures:	Injection	12000 psi
	Hold	6000 psi
	Clamp	225 tons
	Back	75 psi
Times:	Inject	2 sec
	Hold	10 sec
	Closed	30 sec
Mold Temperature:		100°F

The appearance of the molded parts was good with no visible distortion in the PET sell. There were no problems in part removal. However, there was no bond developed between the shell and liner, and the slight difference in shrinkage between the two materials tended to cause separation.

A Saran coating from solvent on the inside of the PET tray was tried on several moldings to evaluate this as an additional barrier layer. Moldings were made with the Saran coating both air dried at room temperature and baked at 200°F to remove any residual solvent. The use of a Saran coating appeared to improve the bond between layers. No difference was observed between air dried and baked coatings.

In an attempt to lock the two molded layers together, the edge of the outer PET tray was beveled and somewhat reduced in size. This provided a space for the polypropylene to flow around the edge of the PET giving an overlap seal. This system was tried with both plain and Saran coated shells giving the best appearance obtained in the double shot series.

Molding Trays Over Barrier Film

Trays 5" x 6" x 0.09" in size were molded from both talc-filled polypropylene (PD491) and from "FDA" glass-filled PET (PDX78732). Molding cycles were similar to those detailed. During the PD491 run, several experimental shots were made with Saran sheet (PSD–560)

and Saranex film (5x–14) held in the bottom of the cavity by vacuum, until the vents plugged, and then by adhesive. Evaluation of these may indicate the feasibility of molding polypropylene into thin-wall thermoformed shells of Saranex to gain barrier properties. No problems were encountered during molding except for plugged vacuum holes.

Heat Sealing Trials

Another requirement for the tray material was heat sealability using an FDA-approved film, preferably a coated foil system. Selected tray materials were tested for bond against coated foils; retortable pouch material from Continental Group and Safe-gard 456M from 3M Co. Seals were made using a heated bar 3/16" x 4" under 50 psi contact pressure and a dwell time of three seconds – bottom side cold. The results were as follows:

Heat Seal Evaluation

	460°F		560°F
	Cont. Foil	456M	Cont. Foil
Udel 1700 Polysulfone	3	3	3
PD 491 Polypropylene	1	2	–
PT–18 TPX	3	3	3
25–04 Acetal	3	2	2
RL4087 Polycarbonate	3	3	3

Rating Code: 1 = Good
2 = Fair – some adhesion
3 = Poor – no bond

The above results indicated that a heat-seal development program would be required if any material other than polypropylene were to be used for the inside (seal surface) of the molded tray.

An additional sample of 0.004 heat seal foil was received from Continental (medical packaging grade produced for Kendall) and tried on both polypropylene and PET. Good seals were made at 450°F/40 psi/3 second to polypropylene, but the adhesion to PET was very poor. A sample of 0.00075 heat-sealable oven film was received from 3M Co. (Scotchpak #5840) and evaluated. A good seal was achieved with PET at 370°F/30 psi/1 second, but almost no adhesion to polypropylene.

In addition, samples of PPRO and PET molded trays were sent to 3M Co. for heat seal foil/film evaluation.

Molded Samples and Test Results

Samples of 0.045-in and 0.090-in single and double shot molded trays were forwarded to Natick Laboratories to be evaluated for dimensional stability under sterilization conditions, i.e., 250°F pressurized water retort.

The prototype mold installed and molded 5" x 6" trays prior to gate removal are shown in the following photos (Figures 4 and 5).

Trays forwarded to Natick Laboratories for test are described as follows – reference: Figure 6 and Table 7. The results of these tests are given in Table 8. In addition, the double-shot technique with a Saran coating between the layer (sample 7 and 8) came closest to performing satisfactorily. Bond strength improvement, however, is needed to withstand the stresses of thermal processing. This weakness might possibly be overcome by application of an adhesive, surface treatment, or selection of other molding materials. Further work in search of an appropriate material appears warranted.

SUMMARY AND RECOMMENDATIONS

A design for an injection molded three-piece half steamtable storage tray has been proposed Reference: DWG. ND–A4–D. In the absence of a material selection recommendation, NARADCOM has decided not to fund the construction of full-scale tooling and sample production. A prototype mold for quarter size trays has been produced, and trays molded for evaluation.

We recommend that the prototype tooling be retained either at Springborn Laboratories, Inc. or NARADCOM to permit either an evaluation of a new candidate material if and when available, or improvements in the double-shot molding technique, particularly in the area of bonding between shell and liner.

Figure 4. 5" x 6" tray mold in Beloit 325 RS25 injection molding machine

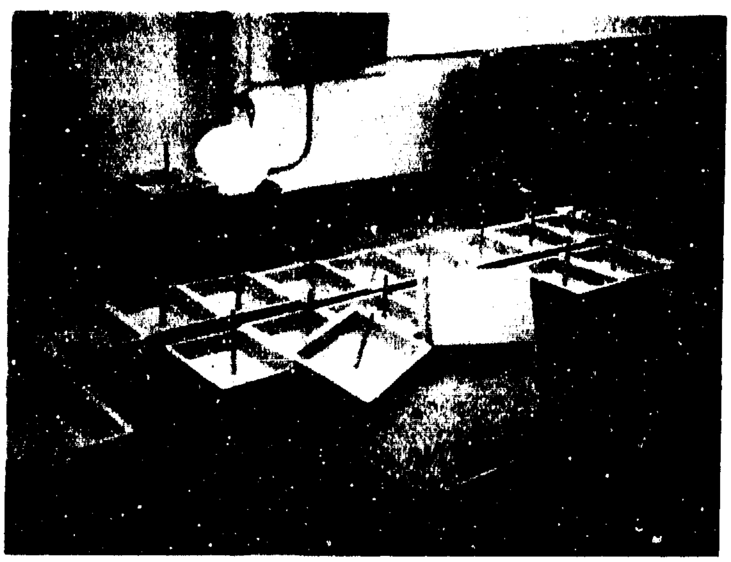

Figure 5. 5" x 6" injection molded trays

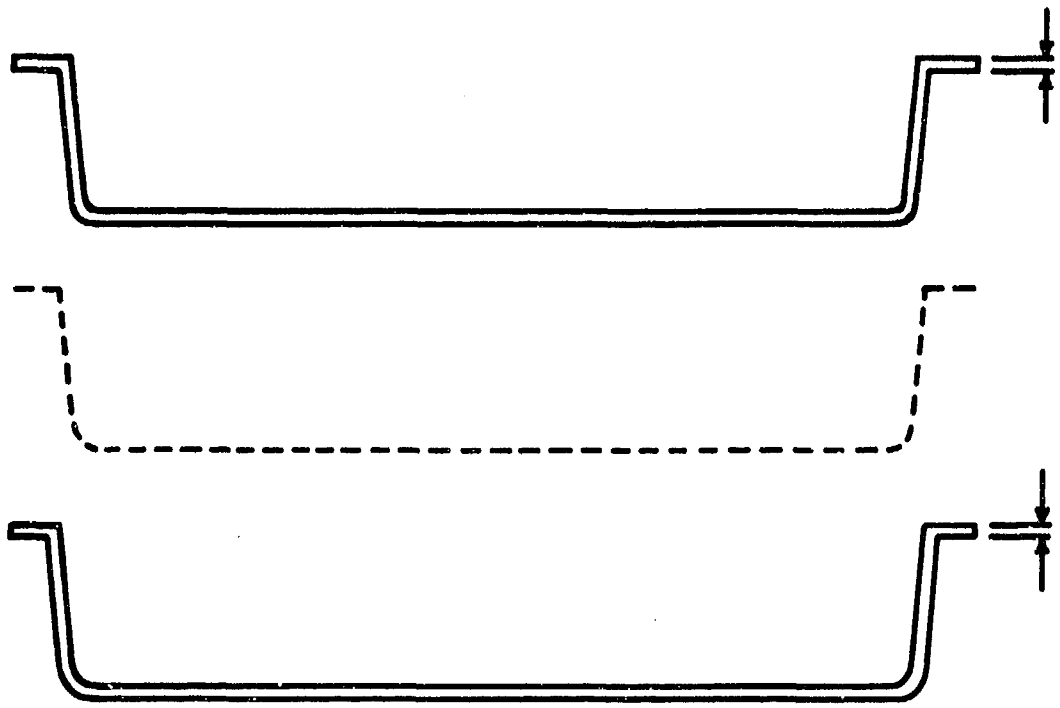

Figure 6. Cross-section view – experimental 5" x 6" x 1.2" (1/8 steamtable size) composite tray

Table 7

Description, Experimental Steamtable Tray

Lab Code #	Description Ref: Figure 6	
1	A	0.045-in thick PDX78732
	B	None
	C	None
2	A	0.090-in thick PD491
	B	None
	C	None
3	A	0.090-in thick PDX78732
	B	None
	C	None
4	A	0.090-in thick PDX78732
	B	Saran Coating from Solvent
	C	None
5	A	0.045-in thick PD491
	B	None
	C	0.045-in thick PDX78732
6	A	0.045-in thick PD491 (Beveled edge)
	B	None
	C	0.045-in thick PDX 78732
7	A	0.045-in thick PD491
	B	Saran Coating from Solvent
	C	0.045-in thick PDX78732
8	A	0.045-in thick PD491 (Beveled edge)
	B	Saran Coating from Solvent
	C	0.045-in thick PDX78732
9	A	0.090-in thick PD491
	B	0.002-in Saranex Film
	C	None
10	A	0.090-in thick PD491
	B	0.006-in Saran Film
	C	None

Material Code:

PDX78732 LNP Corp., Malvern, PA 19355
Designation for a blend of Polyethylene Terephthalate-Goodyear Tire & Rubber Chemical Div., Akron, Ohio 44316
VFR5877—Cleartuf 72 with 30% fiberglass-Owens-Corning Fiberglass Corp., Toledo, Ohio 43659.

Table 7

Description, Experimental Steamtable Tray (cont'd)

Material Code:	
PD491	40% Talc (3 $MgSiO_3$ $5H_2O$) filled Polypropylene — Hercules Inc., Magna, Utah 84044
Saran Coating	Saran Resin F239 — Dow Chemical Co., Midland, Michigan 48640. 18% solids in a 65:35 Tetrahydrofurance. Toluene solvent mix.
Saran Film	0.006 PSD560 Saran sheet — Dow Chemical Co., Midland, Michigan 48640
Saranex Film	X02004.23 (5 x 14) Polyethylene/Saran/Ethylene Vinyl Acetate "sandwich" — Dow Chemical Co., Midland, Michigan 48640

Table 8

Product Process Test

The results of thermoprocess testing at 121°C (250°F) in water for one hour are reported. These tests were performed at Natick on samples prepared by Springborn Laboratories, Inc.

Lab Code No.	Results
1. 0.045-in PDX78732	Heat distortion excellent – no change in color or other physical characteristics.
2. 0.09-in PD491 trays	Same as above.
3. 0.09-in PDX78732	Same as above.
4. 0.90-in PDX78732	Saran coating on interior of PET tray changed from a clear to milky color. This was apparently due to moisture pickup (blushing) and could be driven out by application of heat. The coating, however, was firmly adhered to the PET and could not be scratched off with a fingernail.
5. 0.09-in PDX78732/PD491	Not tested – no adhesion between PDX78732 and PD491 layers.
6. 0.09-in PDX78732/PD491 Bevel edge	Bevel edge locks (inner ply to outer PET); however, liquid seal is not made and water enters between layer.
7. 0.09-in PDX78732/Saran/PD491	In tearing down, there was indication that Saran adhered to the PP but not PET. In addition, there was considerable shrinking of the Saran coating. Water also entered between the Saran and PET layers.
8. 0.09-in PDX78732/Saran/PD491	Same as above, except bevel edge locked inner PP to outer PET.
9. 0.09-in PD491/Saranex Sheet	Saranex adhered to outer surface of PP. Peel strength rather weak – peels off easily – no apparent shrinking.
10. 0.09-in PD491/Saran Sheet	Saran material that adhered to outside of PP shrank considerably and peeled completely from PP.

APPENDIX A

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APPENDIX A

THE FOOD CHEMICAL NEWS G U I D E

ACEPHATE (CONT.)

CHEVRON'S ORTHO PETITION NOV. 3, 1975, WOULD SET A TOLERANCE OF 16 P.P.M. FOR RESIDUES OF THE INSECTICIDE IN TOMATO POMACE.

CHEVRON CHEMICAL PETITION MAY 26, 1976, AS AMENDED JUNE 28, 1979, WOULD AMEND §561.20 (ACEPHATE) TO SET A TOLERANCE OF 3 P.P.M. IN DRIED CITRUS PULP FOR THE INSECTICIDE, WITH NOT MORE THAN 1 P.P.M. OF THE RESIDUE TO BE THE METABOLITE O,S-DIMETHYL PHOSPHORAMIDOTHIOATE.

ACESULFAME POTASSIUM

American Hoechst Petition Oct. 15, 1982, would clear use of the potassium salt of 6-methyl-1,2,3-oxathiazine-4(3H)-one-2,2-dioxide as a nonnutritive sweetener.

ACETAL

CLEARED UNDER §172.515 (SYNTHETIC FLAVORING SUBSTANCES AND ADJUVANTS) (FR OCT. 27, 1964).

ACETALDEHYDE (ETHANAL)

GENERALLY RECOGNIZED AS SAFE UNDER §182.60 (SYNTHETIC FLAVORING SUBSTANCES AND ADJUVANTS).

GENERALLY RECOGNIZED AS SAFE FOR USE IN ANIMAL FEEDS UNDER §582.60 (SYNTHETIC FLAVORING SUBSTANCES AND ADJUVANTS).

ACETALDEHYDE BENZYL β-METHOXYETHYL ACETAL

CLEARED UNDER §172.515 (SYNTHETIC FLAVORING SUBSTANCES AND ADJUVANTS) (FR OCT. 27, 1964).

ACETALDEHYDE, BUTYL PHENETHYL ACETAL

DEEMED TO BE GENERALLY RECOGNIZED AS SAFE BY THE FLAVOR AND EXTRACT MANUFACTURERS ASSOCIATION.

ACETALDEHYDE DIETHYL ACETAL

CLEARED UNDER §172.515 (SYNTHETIC FLAVORING SUBSTANCES AND ADJUVANTS) (FR OCT. 27, 1964).

ACETALDEHYDE DIMETHYL ACETAL

DEEMED TO BE GENERALLY RECOGNIZED AS SAFE BY THE FLAVOR AND EXTRACT MANUFACTURERS ASSOCIATION.

TALDEHYDE PHENETHYL PROPYL ACETAL

CLEARED UNDER §172.515 (SYNTHETIC FLAVORING SUBSTANCES AND ADJUVANTS) (FR OCT. 27, 1964).

ACETANISOLE

CLEARED UNDER §172.515 (SYNTHETIC FLAVORING SUBSTANCES AND ADJUVANTS) (FR OCT. 27, 1964).

ACETIC ACID (CAS Reg. No. 64-19-7)

General recognition of safety is affirmed under §184.1005 (ACETIC ACID) as follows (FR June 25, 1982):

Definition: $C_2H_4O_2$, also known as ethanoic acid and occurring naturally in plant and animal tissues or produced by the fermentation of carbohydrates or by organic synthesis, with the principal synthetic methods current employed being oxidation of acetaldehyde derived from ethylene, liquid phase oxidation of butane, and reaction of carbon monoxide with methanol derived from natural gas.

Specifications: meets Food Chemicals Codex specifications.

Uses and limitations: used as a curing and pickling agent; flavor enhancer; flavoring agent and adjuvant; pH control agent; solvent and vehicle; and boiler water additive in food at levels not to exceed current good manufacturing practice, which results in maximum levels, as served, of 0.25 percent in baked goods; 0.8 percent in cheeses and dairy product analogs; 0.5 percent in chewing gum; 9.0 percent in condiments and relishes; 0.5 percent in fats and oils; 3.0 percent in gravies and sauces; 0.6 percent in meat products and 0.15 percent or less for all other food categories and as a boiler water additive at levels not to exceed current good manufacturing practices.

GENERALLY RECOGNIZED AS SAFE FOR USE IN ANIMAL FEED UNDER §582.1005 (ACETIC ACID).

EXEMPTED FROM TOLERANCE REQUIREMENTS UNDER §182.99 (ADJUVANTS FOR PESTICIDE CHEMICALS) WHEN USED AS A CATALYST IN PESTICIDE USE DILUTIONS BY A GROWER OR APPLICATOR PRIOR TO APPLICATION TO THE RAW AGRICULTURAL COMMODITY.

CALCIUM CARBONATE (CAS Reg. No. 471-34-1)

Granted prior sanction as a stabilizer and listed in §181.29 (STABILIZERS)

Generally recognized as safe status tentatively affirmed under §184.1190 (CALCIUM CARBONATE), as follows (FR Aug. 31, 1982):

Definition: $CaCO_3$, prepared by three common methods of manufacture: (1) as a byproduct in the lime soda process; (2) by precipitation of calcium carbonate from calcium hydroxide in the carbonate process or (3) by precipitation of calcium carbonate from calcium chloride in the calcium chloride process.

Specifications: meets Food Chemicals Codex specifications.

Uses and limitations: use in food generally in accordance with current good manufacturing practice.

GRAS listings for calcium carbonate under §182.1191 and §182.8191 would be deleted.

Generally recognized as safe as a miscellaneous and/or general purpose food additive under §182.1191 (CALCIUM CARBONATE).

Generally recognized as safe as a dietary supplement under §182.5191 (CALCIUM CARBONATE).

Generally recognized as safe as a nutrient under §182.81919(CALCIUM CARBONATE).

Generally recognized as safe as a general purpose feed additive under §582.1191 (CALCIUM CARBONATE).

Generally recognized as safe as a nutrient and/or dietary supplement in animal feed under §582.5191 (CALCIUM CARBONATE).

EXEMPTED FROM TOLERANCE REQUIREMENTS UNDER §182.99 (ADJUVANTS FOR PESTICIDE CHEMICALS) WHEN USED AS A SOLID DILUENT OR CARRIER IN PESTICIDE FORMULATIONS.

CLEARED UNDER §240.1051 (MATERIALS AUTHORIZED FOR TREATMENT OF WINE) TO REDUCE THE EXCESS NATURAL ACIDS IN HIGH ACID WINE, WITH THE NATURAL OR FIXED ACIDS NOT TO BE REDUCED BELOW 5 PARTS PER 1,000, SUBJECT TO LIMITATIONS IN §182.1191 (CALCIUM CARBONATE).

CLEARED AS A PIGMENT AND COLORANT UNDER §175.300 (RESINOUS AND POLYMERIC COATINGS), §175.380 (XYLENE-FORMALDEHYDE RESINS CONDENSED WITH 4,4'-ISOPROPYLIDENEDIPHENOL EPICHLOROHYDRIN EPOXY RESINS), §175.390 (ZINC-SILICON DIOXIDE MATRIX COATINGS), §176.170 (COMPONENTS OF PAPER AND PAPERBOARD IN CONTACT WITH AQUEOUS AND FATTY FOODS), §177.1210 (CLOSURES WITH SEALING GASKETS FOR FOOD CONTAINERS), §177.1350 (ETHYLENE-VINYL ACETATE COPOLYMERS) AND §177.1460 (MELAMINE-FORMALDEHYDE RESINS IN MOLDED ARTICLES).

CLEARED UNDER §177.1600 (POLYETHYLENE RESINS, CARBOXYL MODIFIED).

EXEMPTED FROM TOLERANCE REQUIREMENTS UNDER §182.99 (ADJUVANTS FOR PESTICIDE CHEMICALS) WHEN USED AS A SOLID DILUENT OR CARRIER.

FDA PROPOSAL JUNE 6, 1972, WOULD CLEAR USE UNDER AN ORDER FOR COLORANTS FOR PLASTICS.

CALCIUM CASEINATE

GRANTED PRIOR SANCTION VIA CLEARANCE FOR OPTIONAL USE IN FROZEN DESSERTS UNDER FOOD STANDARDS §135.

GENERAL RECOGNITION OF SAFETY FOR USE IN DIETARY SUPPLEMENTS AFFIRMED BY FDA LETTER TO TRADE ASSOCIATION.

POLYBUTENE, HYDROGENATED (CONT.)

Hydrogenated polybutene with a minimum viscosity at 210° F of 39 Saybolt Universal seconds, as determined by ASTM Methods D-445 and D-2161, and a bromine number of 3 or less, as determined by ASTM Method D-1492, is cleared under §178.3910 (SURFACE LUBRICANTS USED IN THE MANUFACTURE OF METALLIC ARTICLES).

POLY-1-BUTENE RESINS

CLEARED FOR INDIRECT ADDITIVE USES UNDER §177.1570 (POLY-1-BUTENE RESINS BUTENE/ETHYLENE COPOLYMERS) (FR FEB. 10, 1972). THE RESINS ARE PRODUCED BY THE CATALYTIC POLYMERIZATION OF BUTENE-1 LIQUID MONOMER. THE RESINS CAN BE IDENTIFIED BY THEIR CHARACTERISTIC INFRARED SPECTRA. THEY MUST HAVE: INTRINSIC VISCOSITY OF 1.0-3.2 AS DETERMINED BY ASTM METHOD D-1601; DENSITY OF 0.904 TO 0.920 GMS/GM^3 AS DETERMINED BY ASTM METHOD D-1505-63T; AND A MELT INDEX OF 0.1 TO 24 AS DETERMINED BY ASTM METHOD D-1238, CONDITION E. THE RESINS ARE CLEARED AS FOLLOWS:

(1) AS ARTICLES OR COMPONENTS OF ARTICLES INTENDED FOR FOOD CONTACT, WITH A MAXIMUM EXTRACTABLE NOT TO EXCEED 2.5% BY WEIGHT OF THE POLYMER WHEN FILM OR MOLDED SAMPLES ARE TESTED FOR TWO HOURS AT 50°C IN N-HEPTANE.

(2) AS ARTICLES OR COMPONENTS OF ARTICLES FOR PACKAGING OR HOLDING FOOD DURING COOKING, PROVIDED THAT THE THICKNESS OF THE POLYMERS IN THE FORM IN WHICH THEY CONTACT FOOD DOES NOT EXCEED 4 MILS AND MAXIMUM EXTRACTABLES DO NOT EXCEED 2.5% BY WEIGHT OF THE POLYMER WHEN FILMS ARE EXTRACTED FOR TWO HOURS AT 50°C IN N-HEPTANE.

POLYBUTYLATED (MIXTURE) 4,4'-ISOPROPYLIDENEDIPHENOL

CLEARED AS AN ANTIOXIDANT OR ANTIOZONANT IN THE PREPARATION OF RUBBER ARTICLES UNDER §177.2600 (RUBBER ARTICLES INTENDED FOR REPEATED USE). TOTAL ANTIOXIDANTS AND ANTIOZONANTS NOT TO EXCEED 5% BY WEIGHT OF RUBBER PRODUCT.

POLYBUTYLENE GLYCOL

POLYBUTYLENE GLYCOL (MOLECULAR WEIGHT 1,000) CLEARED UNDER §175.105 (ADHESIVES).

CLEARED AS A SUBSTANCE WITH WHICH ISOCYANATES ARE REACTED TO FORM RESINS UNDER §177.1680 (POLYURETHANE RESINS) (FR APRIL 16, 1974).

POLYCARBONATE FILM, COATED

PETITION WITHDRAWN FEB. 2, 1967, WOULD HAVE CLEARED USE IN FOOD PACKAGING.

→ POLYCARBONATE RESINS

POLYCARBONATE RESINS COMPLYING WITH §177.1580 (POLYCARBONATE RESINS) CLEARED UNDER §177.1200 (CELLOPHANE) AND §177.1400 (WATER-INSOLUBLE HYDROXYETHYL CELLULOSE FILM) (FR SEPT. 12, 1964).

CLEARED UNDER §177.1580 (POLYCARBONATE RESINS) AS ARTICLES OR COMPONENTS OF ARTICLES FOR USE IN PRODUCING, MANUFACTURING, PACKING, PROCESSING, PREPARING, TREATING, PACKAGING, TRANSPORTING, OR HOLDING FOOD. POLYCARBONATE RESINS ARE POLYESTERS PRODUCED BY: (1) THE CONDENSATION OF 4,4'-ISOPROPYLIDENEDIPHENOL AND CARBONYL CHLORIDE, TO WHICH MAY HAVE BEEN ADDED CERTAIN OPTIONAL ADJUVANT SUBSTANCES REQUIRED IN THE PRODUCTION OF THE RESINS; (2) THE REACTION OF MOLTEN 4.4-ISOPROPYLIDENEDIPHENOL WITH MOLTEN DIPHENYL CARBONATE IN THE PRESENCE OF 4,4'-ISOPROPYLIDENE DISODIUM SALT (FR MAY 27, 1967); OR (3) THE CONDENSATION OF 4,4'-ISOPROPYLIDENEDIPHENOL, CARBONYL CHLORIDE, AND 0.5% WEIGHT MAXIMUM OF GA,G6-BIS(6-HYDROXY-M-TOLYL)MESITOL TO WHICH MAY HAVE BEEN ADDED OPTIONAL SUBSTANCES REQUIRED IN THE PRODUCTION OF BRANCHED POLYCARBONATE RESINS (FR MAY 13, 1970). THE RESINS ARE USED UNDER THE FOLLOWING PRESCRIBED CONDITIONS: (A) SPECIFICATIONS: POLYCARBONATE RESINS CAN BE IDENTIFIED BY THEIR CHARACTERISTIC INFRARED SPECTRUM; (B) EXTRACTIVES LIMITATIONS: THE POLYCARBONATE RESINS TO BE TESTED SHALL BE GROUND OR CUT INTO SMALL PARTICLES THAT WILL PASS THROUGH A U.S. STANDARD SIEVE NO. 6 AND THAT WILL BE HELD ON A U.S. STANDARD SIEVE NO. 10: (1) POLYCARBONATE RESINS, WHEN EXTRACTED WITH DISTILLED WATER AT REFLUX TEMPERATURE FOR 6 HOURS SHALL YIELD TOTAL EXTRACTIVES NOT TO EXCEED 0.15% BY WEIGHT OF THE RESINS; (2) POLYCARBONATE RESINS WHEN EXTRACTED WITH N-HEPTANE AT REFLUX TEMPERATURE FOR 6 HOURS SHALL YIELD TOTAL EXTRACTIVES NOT TO EXCEED 0.15% BY WEIGHT OF THE RESINS; (3) POLYCARBONATE RESINS WHEN EXTRACTED WITH 50% (BY VOLUME) ETHYL ALCOHOL IN DISTILLED WATER AT REFLUX TEMPERATURE FOR 6 HOURS SHALL YIELD TOTAL EXTRACTIVES NOT TO EXCEED 0.15% BY WEIGHT OF THE RESINS; (C) THE OPTIONAL ADJUVANT SUBSTANCES REQUIRED IN THE PRODUCTION OF THE RESINS MAY INCLUDE SUBSTANCES GENERALLY RECOGNIZED AS SAFE IN FOOD, SUBSTANCES USED IN ACCORDANCE WITH A PRIOR SANCTION, AND THE FOLLOWING:

P-TERT-BUTYLPHENOL.
CHLOROFORM.
ETHYLENE DICHLORIDE.
HEPTANE.
METHYLENE CHLORIDE.
MONOCHLOROBENZENE, AT LEVELS NOT IN EXCESS OF 500 P.P.M. AS A RESIDUAL SOLVENT IN FINISHED RESIN.
PYRIDINE.
TOLUENE, AS A RESIDUAL SOLVENT IN FINISHED RESIN AT A LEVEL NOT TO EXCEED 800 P.P.M.
TRIETHYLAMINE.

POLY(METHYLENE-P-NONYLPHENOXY)-POLY(OXYETHYLENE)PROPANOL

POLY(METHYLENE-P-NONYLPHENOXY)-POLY(OXYETHYLENE)PROPANOL, WITH THE POLY(OXYETHYLENE) CONTENT AVERAGING 4-12 MOLES, IS EXEMPTED FROM TOLERANCE REQUIREMENTS UNDER §182.99 (ADJUVANTS FOR PESTICIDE CHEMICALS) WHEN USED IN PESTICIDE FORMULATIONS APPLIED TO GROWING CROPS, AND UNDER §582.99 WHEN APPLIED TO ANIMALS (FR JUNE 6, 1972).

POLY((METHYLENE-P-NONYLPHENOXY)POLY(OXYPROPYLENE)(4-12 MOLES)PROPANOL)

POLY((METHYLENE-P-NONYLPHENOXY)POLY(OXYPROPYLENE)(4-12 MOLES)PROPANOL) HAVING A MINIMUM MOLECULAR WEIGHT OF 8500 IS CLEARED FOR USE IN COATINGS AT LEVELS NOT TO EXCEED 1 MG PER SQUARE FOOD OF FOOD-CONTACT SURFACE UNDER §178.3400 (EMULSIFIERS AND/OR SURFACE-ACTIVE AGENTS) (FR DEC. 15, 1978).

POLY(N-METHYLETHYLENE AMMONIUM) CHLORIDE

PETITION WITHDRAWN AUG. 12, 1977, FILED BY NALCO CHEMICAL SEPT. 10, 1976, WOULD HAVE CLEARED AS A PROCESSING AID IN THE MANUFACTURE OF SILICA AND SILICATES FOR FOOD ADDITIVE USE.

POLY(METHYLIMINO)(2-HYDROXYTRIMETHYLENE)HYDROCHLORIDE

POLY(METHYLIMINO)(2-HYDROXYTRIMETHYLENE)HYDROCHLORIDE) PRODUCED BY REACTION OF 1:1 MOLAR RATIO OF METHYLAMINE AND EPICHLOROHYDRIN SO THAT A 31% AQUEOUS SOLUTION AT 25°C HAS A STOKES VISCOSITY RANGE OF 2.5-4.0 AS DETERMINED BY ASTM METHOD D-1545-63 IS CLEARED UNDER §176.170 (COMPONENTS OF PAPER AND PAPERBOARD IN CONTACT WITH AQUEOUS AND FATTY FOODS) AND §176.180 (COMPONENTS OF PAPER AND PAPERBOARD IN CONTACT WITH DRY FOOD) AS A RETENTION AID EMPLOYED PRIOR TO THE SHEET-FORMING OPERATION IN SUCH AN AMOUNT THAT THE FINISHED PAPER AND PAPERBOARD WILL CONTAIN THE ADDITIVE AT A LEVEL NOT IN EXCESS OF 1% BY WEIGHT OF DRY PAPER AND PAPERBOARD (FR JULY 28, 1971).

POLY(METHYLPENTENE)

POLY(METHYLPENTENE) CONSISTING OF BASIC POLYMERS MANUFACTUREF BY THE CATALYTIC POLYMERIZATION OF 4-METHYLPENTENE-1 CLEARED FOR INDIRECT ADDITIVE USE UNDER §177.1520 (OLEFIN POLYMERS) (FR MAY 7, 1968). THE POLYMERS MUST HAVE A DENSITY OF 0.82-0.85; MELTING POINT 235°-250°C; MAXIMUM EXTRACTABLE FRACTION IN N-HEXANE 6.6% AT REFLUX TEMPERATURE; AND MAXIMUM SOLUBLE FRACTION IN XYLENE OF 7.5% AT 25°C.

POLY(α-METHYLSTYRENE)

PETITION WITHDRAWN JUNE 29, 1979, FILED BY GOODYEAR TIRE AND RUBBER SEPT. 10, 1976, WOULD HAVE AMENDED §177.1640 (POLYSTYRENE AND RUBBER-MODIFIED POLYSTYRENE) TO CLEAR POLY(α-METHYLSTYRENE) AS AN OPTIONAL INGREDIENT IN RUBBER-MODIFIED POLYSTYRENE.

POLY(P-METHYLSTYRENE)

MOBIL CHEMICAL PETITION MARCH 12, 1982, WOULD CLEAR INDIRECT ADDITIVE USE OF POLY(P-METHYLSTYRENE) AND RUBBER-MODIFIED POLY(P-METHYLSTYRENE).

POLY-1,4,7,10,18-PENTAAZA-15-HYDROXYHEXADECANE

CLEARED UNDER §176.250 (POLY-1,4,7,10,18-PENTAAZA-15-HYDROXYHEXADECANE) AS A RETENTION AID EMPLOYED PRIOR TO THE SHEET-FORMING OPERATION IN THE MANUFACTURE OF PAPER AND PAPERBOARD INTENDED FOR USE IN CONTACT WITH FOOD, IN AN AMOUNT NOT TO EXCEED THAT NECESSARY TO ACCOMPLISH THE INTENDED PHYSICAL OR TECHNICAL EFFECT, AND NOT TO EXCEED 6 POUNDS PER TON OF FINISHED PAPER AND PAPERBOARD.

POLYPHENYLENE SULFIDE RESINS

POLYPHENYLENE SULFIDE RESINS CLEARED UNDER §177.2490 (POLYPHENYLENE SULFIDE RESINS) (FR OCT. 19, 1972) AS COATINGS OR COMPONENTS OF COATINGS OF ARTICLES INTENDED FOR REPEATED USE IN CONTACT WITH FOOD. THE RESINS (POLY(1,4-PHENYLENE SULFIDE) RESINS) ARE TO CONSIST OF BASIC RESINS PRODUCED BY THE REACTION OF EQUIMOLAR PARTS OF P-DICHLOROBENZENE AND SODIUM SULFIDE, SUCH THAT THE FINISHED RESINS MEET THE FOLLOWING SPECIFICATIONS AS DETERMINED BY METHODS AVAILABLE UPON REQUEST FROM THE COMMISSIONER OF FOOD AND DRUGS: (1) SULFUR CONTENT: 28.2-29.1 PERCENT BY WEIGHT OF THE FINISHED RESIN; (2) MINIMUM INHERENT VISCOSITY: 0.18 DECILITERS PER GRAM; (3) MAXIMUM RESIDUAL P-DICHLOROBENZENE: 0.8 P.P.M. THE FOLLOWING SUBSTANCES MAY BE USED AS OPTIONAL SUBSTANCES ADDED TO THE POLYPHENYLENE SULFIDE BASIC RESINS IN AN AMOUNT NOT TO EXCEED THAT REASONABLY REQUIRED TO ACCOMPLISH THE INTENDED PHYSICAL OR TECHNICAL EFFECT: (1) SUBSTANCES GENERALLY RECOGNIZED AS SAFE IN FOOD; (2) SUBSTANCES USED IN ACCORDANCE WITH PRIOR SANCTION OR APPROVAL; AND (3) SUBSTANCES WHOSE USE IS PERMITTED IN COATINGS UNDER REGULATIONS IN PART 121. THE RESINS MAY BE USED IN CONTACT WITH FOOD AT TEMPERATURES NOT TO EXCEED THE BOILING POINT OF WATER; PROVIDED THAT THE FINISHED CURED COATING, WHEN EXTRACTED AT REFLUX TEMPERATURES FOR 8 HOURS SEPARATELY WITH DISTILLED WATER, 50 PERCENT ETHANOL IN WATER, AND 3 PERCENT ACETIC ACID, YIELDS TOTAL EXTRACTIVES IN EACH EXTRACTION SOLVENT NOT TO EXCEED 0.02 MILLIGRAM PER SQUARE INCH OF SURFACE AND WHEN EXTRACTED AT REFLUX TEMPERATURE FOR 8 HOURS WITH HEPTANE YIELDS TOTAL EXTRACTIVES NOT TO EXCEED 0.1 MILLIGRAM PER SQUARE INCH OF SURFACE. THE RESIN COATINGS CONTAINING PERFLUOROCARBON RESINS COMPLYING WITH §177.1550 (PERFLUOROCARBON RESINS) MAY BE USED IN CONTACT WITH FOOD AT TEMPERATURES UP TO AND INCLUDING NORMAL BAKING AND FRYING TEMPERATURES; PROVIDED THAT THE FINISHED CURED COATING, WHEN EXTRACTED AT REFLUX TEMPERATURES FOR 2 HOURS SEPARATELY WITH DISTILLED WATER, 50 PERCENT ETHANOL IN WATER, 3 PERCENT ACETIC ACID AND HEPTANE YIELDS TOTAL EXTRACTIVES IN EACH EXTRACTING SOLVENT NOT TO EXCEED 0.2 MILLIGRAM PER SQUARE INCH OF SURFACE AND WHEN EXTRACTED AT REFLUX TEMPERATURES FOR 1 HOUR WITH DIPHENYL ETHER YIELDS TOTAL EXTRACTIVES NOT TO EXCEED 4.5 MILLIGRAMS PER SQUARE INCH OF SURFACE.

→ POLYPROPYLENE

CLEARED UNDER §175.300 (RESINOUS AND POLYMERIC COATINGS), §175.380 (XYLENE-FORMALDEHYDE RESINS CONDENSED WITH 4,4'-ISOPROPYLIDENEDIPHENOL EPICHLOROHYDRIN EPOXY RESINS), §175.390 (ZINC-SILICON DIOXIDE MATRIX COATINGS), §176.170 (COMPONENTS OF PAPER AND PAPERBOARD IN CONTACT WITH AQUEOUS AND FATTY FOODS), AND §177.1210 (CLOSURES WITH SEALING GASKETS FOR FOOD CONTAINERS).

POLYPROPYLENE COMPLYING WITH §177.1520 (OLEFIN POLYMERS) CLEARED UNDER §177.1200 (CELLOPHANE) AND §177.1400 (WATER-INSOLUBLE HYDROXYETHYL CELLULOSE FILM) (FR SEPT. 12, 1964).

POLYPROPYLENE MANUFACTURED BY THE CATALYTIC POLYMERIZATION OF PROPYLENE CLEARED FOR INDIRECT ADDITIVE USE UNDER §177.1520 (OLEFIN POLYMERS) (FR FEB. 19, 1966). EXTRACTION LIMITATIONS APPLY TO BASIC POLYMER, BUT OPTIONAL ADJUVANTS REQUIRED IN THE PRODUCTION OF THE BASIC POLYMERS MAY BE USED, PROVIDED THESE ARE COVERED BY OTHER ORDERS, ARE GENERALLY RECOGNIZED AS SAFE , OR HAVE BEEN GRANTED PRIOR SANCTIONS. WHEN POLYPROPYLENE IS USED IN ARTICLES COVERED BY OTHER ORDERS, THEY MUST COMPLY WITH LIMITATIONS IN THOSE ORDERS. THE PROVISIONS OF §177.1520 DO NOT APPLY TO POLYPROPYLENE USED IN COMPLIANCE WITH §175.105 (ADHESIVES). EXTRACTION TESTS MUST BE PERFORMED ON BASIC POLYMERS IN FILM FORM NOT EXCEEDING 4 MILS IN THICKNESS. DENSITY MUST BE DETERMINED BY ASTM METHOD D-1505, USING A HOT-STAGE APPARATUS. THE POLYPROPYLENE MUST HAVE A DENSITY OF 0.880-1.00, A MELTING POINT OF 160-180°C, MAXIMUM EXTRACTABLE FRACTION IN XYLENE OF 9.8% AT 25°C, AND MAXIMUM EXTRACTABLE FRACTION IN N-HEXANE OF 6.4% AT REFLUX TEMPERATURE.

CLEARED UNDER §179.45 (PACKAGING MATERIALS FOR USE IN RADIATION PRESERVATION OF PREPACKAGED FOODS) ALONE OR WITH OTHER SUBSTANCES CLEARED UNDER §177.1520 (OLEFIN POLYMERS). FINISHED FILM, FOR EXPOSURE UP TO 1 MEGARAD RESULTING FROM USE OF GAMMA RADIATION IN FOOD PRESERVATION, MAY CONTAIN ADJUVANT SUBSTANCES WHICH HAVE PRIOR SANCTIONS (§181) OR CLEARED UNDER §178.3740 (PLASTICIZERS IN POLYMERIC SUBSTANCES).

CLEARED IN PACKAGING MEAT PRODUCTS BY THE MEAT INSPECTION DIVISION.

UNION CAMP PETITION NOV. 10, 1981, WOULD CLEAR USE OF POLYAMIDE RESINS DERIVED FROM DIMERIZED VEGETABLE OIL ACIDS, AZELAIC ACID, ETHYLENEDIAMINE AND PIPERAZINE AS THE BASIC RESIN IN COATINGS FOR POLYPROPYLENE FILM IN CONTACT WITH FOOD.

POLYPROPYLENE, MALEIC ANHYDRIDE ADDUCT - SEE MALEIC ANHYDRIDE ADDUCT OF POLYPROPYLENE.

POLYSTYRENE-CO-DISODIUM MALEATE-CO-(α-(P-NONYLPHENYL)-OMEGA-(P-VINYLBENZYL)POLY(OXYETHYLENE))TERPOLYMER
CLEARED UNDER §175.105 (ADHESIVES) (FR FEB. 11, 1977).

POLYSTYRENE FILM
POLYSTYRENE FILM PREPARED FROM STYRENE BASE POLYMER IS CLEARED UNDER §179.45 (PACKAGING MATERIALS FOR USE IN RADIATION PRESERVATION OF PREPACKAGED FOODS) (FR AUG. 14, 1964). MAY BE SUBJECTED TO A DOSE OF IRRADIATION NOT TO EXCEED 1 MEGARAD OF INCIDENTAL GAMMA RADIATION. THE FINISHED FILM MAY CONTAIN ADJUVANT SUBSTANCES USED IN COMPLIANCE WITH (§181) (PRIOR SANCTIONED FOOD-PACKAGING MATERIALS) AND §178.3740 (PLASTICIZERS IN POLYMERIC SUBSTANCES).

POLYSULFIDE POLYMER-POLYEPOXY RESINS
CLEARED AS THE FOOD-CONTACT SURFACE OF ARTICLES INTENDED FOR PACKAGING, TRANSPORTING, HOLDING, OR OTHERWISE CONTACTING DRY FOOD UNDER §177.1650 (POLYSULFIDE POLYMER-POLYEPOXY RESINS), IN ACCORDANCE WITH THE FOLLOWING PRESCRIBED CONDITIONS: (A) POLYSULFIDE POLYMER-POLYEPOXY RESINS ARE THE REACTION PRODUCTS OF LIQUID POLYSULFIDE POLYMERS AND POLYFUNCTIONAL EPOXIDE RESINS, CURED WITH THE AID OF TRI(DIMETHYLAMINOMETHYL) PHENOL, TO WHICH HAVE BEEN ADDED CERTAIN OPTIONAL SUBSTANCES TO IMPART DESIRED TECHNOLOGICAL PROPERTIES TO THE RESINS; (B) THE RESINS ARE USED AS THE FOOD-CONTACT SURFACE FOR DRY FOOD; (C) AN APPROPRIATE SAMPLE OF THE FINISHED RESIN IN THE FORM IN WHICH IT CONTACTS FOOD, WHEN SUBJECTED TO METHOD 6191 IN FEDERAL TEST METHOD STANDARD NO. 141, PUBLISHED IN "VARNISH, LACQUER, AND RELATED MATERIALS-METHODS OF INSPECTION AND SAMPLING" (GENERAL SERVICES ADMINISTRATION, WASHINGTON, D. C.), USING NO. 50 EMERY ABRASIVE IN LIEU OF OTTAWA SAND, SHALL EXHIBIT AN ABRASION COEFFICIENT OF NOT LESS THAN 20 LITERS PER MIL OF FILM THICKNESS; (D) THE OPTIONAL SUBSTANCES WHICH MAY BE ADDED TO THE RESINS MAY INCLUDE SUBSTANCES GENERALLY RECOGNIZED AS SAFE IN FOOD AND FOOD PACKAGING; SUBSTANCES THE USE OF WHICH IS PERMITTED UNDER APPLICABLE REGULATIONS IN THIS PART, PRIOR SANCTIONS, OR APPROVALS; SUBSTANCES LISTED BELOW AND FURTHER IDENTIFIED AS REQUIRED:

- BIS(2-CHLOETHYL) FORMAL.
- BIS(DICHLOROPROPYL) FORMAL, AS A CROSS-LINKING AGENT.
- BUTYL ALCOHOL, AS A SOLVENT.
- CARBON BLACK (CHANNEL PROCESS).
- CHLORINATED PARAFFINS, AS CROSS-LINKING AGENTS.
- EPOXIDIZED LINSEED OIL.
- EPOXIDIZED SOYBEAN OIL.
- EPOXY RESINS AS LISTED IN §175.300 (RESINOUS AND POLYMERIC COATINGS).
- ETHYLENE GLYCOL MONOBUTYL ETHER, AS A SOLVENT.
- MAGNESIUM CHLORIDE.
- METHYL ISOBUTYL KETONE, AS A SOLVENT.
- NAPHTHALENE SULFONIC ACID-FORMALDEHYDE CONDENSATE, SODIUM SALT.
- SODIUM DIBUTYL NAPHTHALENE SULFONATE, AS A WETTING AGENT.
- SODIUM HYDROSULFIDE.
- SODIUM POLYSULFIDE.
- β,β'-γ,γ'-TETRACHLORO NORMAL PROPYL ETHER, AS A CROSS-LINKING AGENT.
- TITANIUM DIOXIDE.
- TOLUENE, AS A SOLVENT.
- TRICHLOROETHANE, AS A CROSS-LINKING AGENT.
- 1,2,3-TRICHLOROPROPANE, AS A CROSS-LINKING AGENT.
- UREA-FORMALDEHYDE RESINS.
- XYLENE, AS A SOLVENT.

→ POLYSULFONE RESINS
CLEARED UNDER §177.2500 (POLYSULFONE RESINS) AS ARTICLES OR COMPONENTS OF ARTICLES INTENDED FOR REPEATED USE IN CONTACT WITH FOOD (FR OCT. 25, 1969). IN ACCORDANCE WITH GOOD MANUFACTURING PRACTICE, THE FINISHED FOOD-CONTACT ARTICLES CONTAINING POLYSULFONE RESINS MUST BE THOROUGHLY CLEANSED PRIOR TO FIRST USE IN CONTACT WITH FOOD. THE POLY(OXY-P-PHENYLENESULFONYL-P-PHENYLENEOXY-P-PHENYLENEISOPROPYLIDENE-P-PHENYLENE) RESINS CONSIST OF BASIC RESINS PRODUCED WHEN THE DISODIUM SALT OF 4,4'-ISOPROPYLIDENEDIPHENOL IS MADE TO REACT WITH 4,4'-DICHLORODIPHENYL SULFONE SO THAT THE FINISHED RESINS HAVE A MINIMUM NUMBER AVERAGE MOLECULAR WEIGHT OF 24,000, AS DETERMINED BY OSMOTIC PRESSURE IN MONOCHLOROBENZENE. FINISHED FOOD-CONTACT ARTICLES, WHEN EXTRACTED AR REFLUX TEMPERATURES FOR 6 HOURS WITH THE SOLVENTS DISTILLED WATER, 50% (BY VOLUME) ETHYL ALCOHOL IN DISTILLED WATER, 3% ACETAIC ACID IN DISTILLED WATER, AND N-HEPTANE, WILL YIELD TOTAL EXTRACTIVES IN EACH SOLVENT NOT TO EXCEED 0.05 MG PER SQUARE INCH OF FOOD-CONTACT SURFACE. A SEPARATE TEST SAMPLE MUST BE USED FOR EACH REQUIRED EXTRACTING SOLVENT. OPTIONAL ADJUVANT SUBSTANCES REQUIRED IN THE PRODUCTION OF THE BASIC RESINS MAY BE USED, INCLUDING SUBSTANCES GENERALLY RECOGNIZED AS SAFE IN FOODS, SUBSTANCES GENERALLY RECOGNIZED AS SAFE FOR FOOD PACKAGES, SUBSTANCES WITH PRIOR SANCTIONS, SUBSTANCES CLEARED UNDER OTHER ORDERS FOR INDIRECT ADDITIVE USES, AND THE FOLLOWING: (1) DIMETHYL SULFOXIDE, NOT TO EXCEED 50 P.P.M. AS RESIDUAL SOLVENT IN FINISHED BASIC RESIN; AND (2) MONOCHLOROBENZENE, NOT TO EXCEED 500 P.P.M. AS RESIDUAL SOLVENT IN FINISHED BASIC RESIN.

Union Carbide Petition June 29, 1982, would amend §177.2500 (POLYSULFONE RESINS) to change the molecular weight specifications and testing requirements.

POLYTERPENE RESINS - SEE TERPENE RESINS

POLYTETRAFLUOROETHYLENE
CLEARED UNDER §175.105 (ADHESIVES).

CLEARED AS A RELEASE AGENT UNDER §175.300 (RESINOUS AND POLYMERIC COATINGS), §175.380 (XYLENE-FORMALDEHYDE RESINS CONDENSED WITH 4,4'-ISOPROPYLIDENEDIPHENOL EPICHLOROHYDRIN EPOXY RESINS), §175.390 (ZINC-SILICON DIOXIDE MATRIX COATINGS), §176.170 (COMPONENTS OF PAPER AND PAPERBOARD IN CONTACT WITH AQUEOUS AND FATTY FOODS), §177.1210 (CLOSURES WITH SEALING GASKETS FOR FOOD CONTAINERS), AND §177.1350 (ETHYLENE-VINYL ACETATE COPOLYMERS).

TALC

GENERALLY RECOGNIZED AS SAFE UNDER §182.70 (SUBSTANCES MIGRATING FROM COTTON FABRICS USED IN DRY FOOD PACKAGING).

GENERALLY RECOGNIZED AS SAFE UNDER §182.90 (SUBSTANCES MIGRATING TO FOOD FROM PAPER AND PAPERBOARD PRODUCTS).

GENERAL RECOGNITION OF SAFETY FOR USE IN DIETARY SUPPLEMENTS AFFIRMED BY FDA LETTER TO TRADE ASSOCIATION.

GENERAL RECOGNITION OF SAFETY OF TALC COMPLYING WITH SPECIFICATIONS IN THE U.S. PHARMACOPOEIA IN CHEWING GUM AFFIRMED BY FDA LETTER TO TRADE ASSOCIATION.

EXEMPTED FROM TOLERANCE REQUIREMENTS UNDER §182.99 (ADJUVANTS FOR PESTICIDE CHEMICALS) WHEN USED AS A SOLID DILUENT OR CARRIER IN PESTICIDE FORMULATIONS AND UNDER §582.99 WHEN USED AS A DILUENT OR CARRIER IN FORMULATIONS APPLIED TO ANIMALS.

CLEARED AS A PIGMENT AND COLORANT UNDER §175.300 (RESINOUS AND POLYMERIC COATINGS), §175.380 (XYLE' FORMALDEHYDE RESINS CONDENSED WITH 4,4'-ISOPROPYLIDENEDIPHENOL EPICHLOROHYDRIN EPOXY RESINS), §175.. (ZINC-SILICON DIOXIDE MATRIX COATINGS), §176.170 (COMPONENTS OF PAPER AND PAPERBOARD IN CONTACT WITH AQUEOUS AND FATTY FOODS), §177.1210 (CLOSURES WITH SEALING GASKETS FOR FOOD CONTAINERS), §177.1350 (ETHYLENE-VINYL ACETATE COPOLYMERS) AND §177.1460 (MELAMINE-FORMALDEHYDE RESINS IN MOLDED ARTICLES).

FDA PROPOSAL AUG. 12, 1972 WOULD (1) ADD TO THE PRESENT §182 GENERALLY RECOGNIZED AS SAFE LISTINGS THE PROVISION THAT THE TALC IS FREE OF ASBESTOS-FORM PARTICLES; (2) LIST TALC UNDER §182 WHICH IS FREE OF ASBESTOS-FORM PARTICLES FOR USE IN CHEWING GUM BASE AND AS AN ANTI-STICKING AGENT IN FORMS USED IN MOLDING FOOD SHAPES; AND (3) ISSUE A §121.2006 ORDER RECOGNIZING PRIOR SANCTIO FOR USE OF TALC IN COATING POLISHED RICE FOR NATURALLY OCCURING HYDROUS MAGNESIUM SILICATE FOR WHICH NO FOOD GRADE SPECIFICATIONS EXIST, WITH A NOTE THAT TALC CONTAINING ASBESTOS-FORM PARTICLES MAY BE HAZARDOUS TO HEALTH. PROPOSAL WAS EXPANDED SEPT. 28, 1973, TO INCLUDE AN ANALYTICAL METHOD WHICH WOULD APPLY TO BOTH PRIOR SANCTIONED AND GENERALLY RECOGNIZED AS SAFE LISTINGS OF TALC. ON MARCH 14, 1975, FDA WITHDREW THE FIRST PART OF THE PROPOSAL, WHICH WOULD HAVE ADDED TO THE §182 LISTINGS THE REQUIREMENT THAT TALC BE FREE OF ASBESTOS-FORM PARTICLES, AND INDICATED THAT THE OTHER TWO PARTS OF THE PROPOSAL WILL BE HELD IN ABEYANCE.

TALL OIL

GRANTED PRIOR SANCTION FOR USE AS A DRYING OIL IN THE MANUFACTURE OF FOOD-PACKAGING MATERIALS AND LISTED IN §181.26 (DRYING OILS AS COMPONENTS OF FINISHED RESINS).

GENERALLY RECOGNIZED AS SAFE UNDER §182.70 (SUBSTANCES MIGRATING FROM COTTON FABRICS USED IN DRY FOOD PACKAGING).

TALL OIL WITH NOT LESS THAN 58% FATTY ACIDS, NOT MORE THAN 44% ROSIN ACIDS AND NOT MORE THAN 8% UNSAPONIFIABLES IS EXEMPTED FROM TOLERANCE REQUIREMENTS UNDER §182.99 (ADJUVANTS FOR PESTICIDE CHEMICALS) WHEN USED AS A SURFACTANT OR RELATED ADJUVANTS OF SURFACTANSS IN FORMULATIONS APPLIED TO GROWING CROPS OR RAW AGRICULTURAL COMMODITIES AFTER HARVEST (FR APRIL 3, 1969) AND UNDER §582.99 WHEN USED IN FORMULATIONS APPLIED TO ANIMALS.

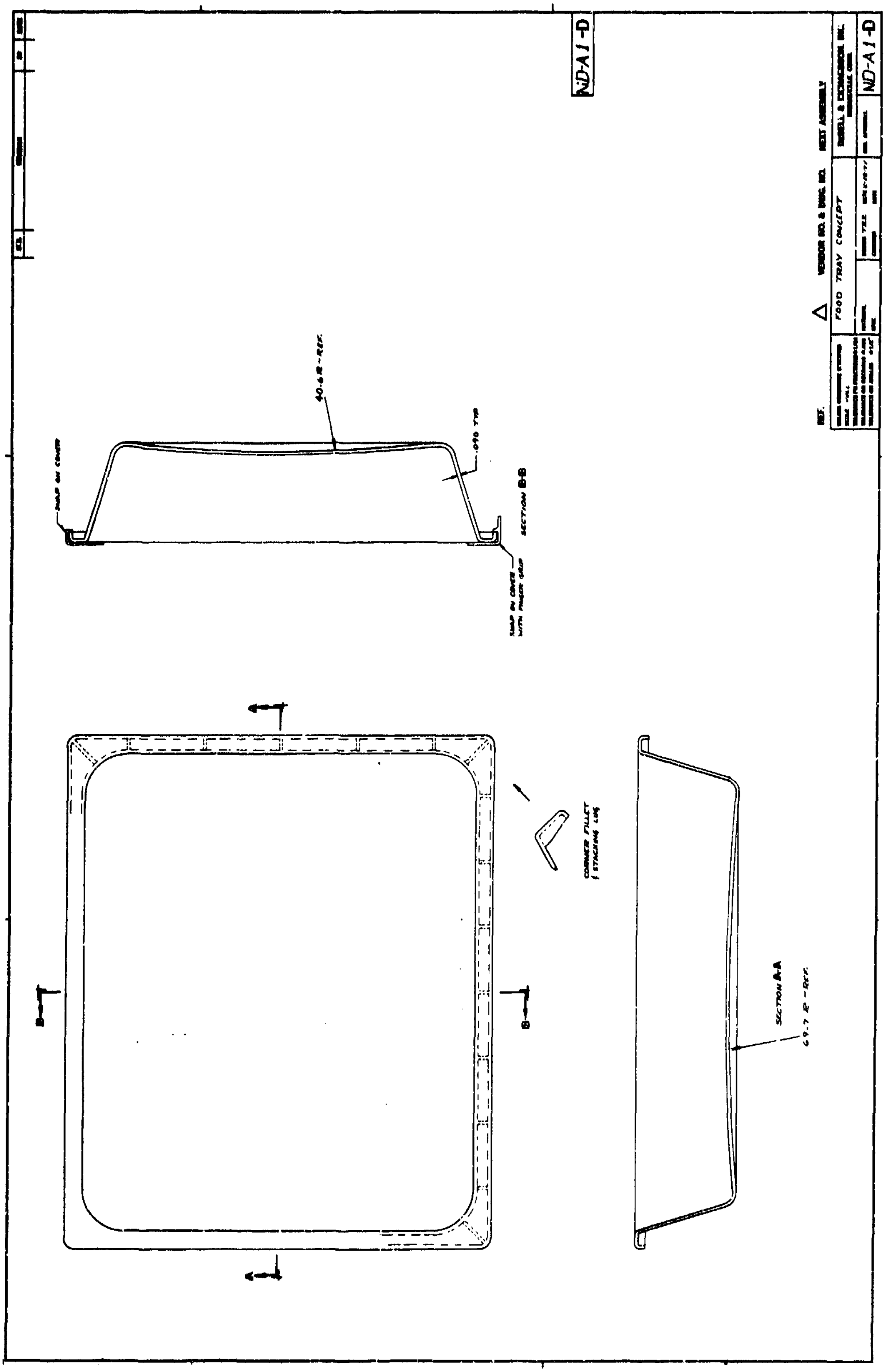
CLEARED UNDER §175.105 (ADHESIVES).

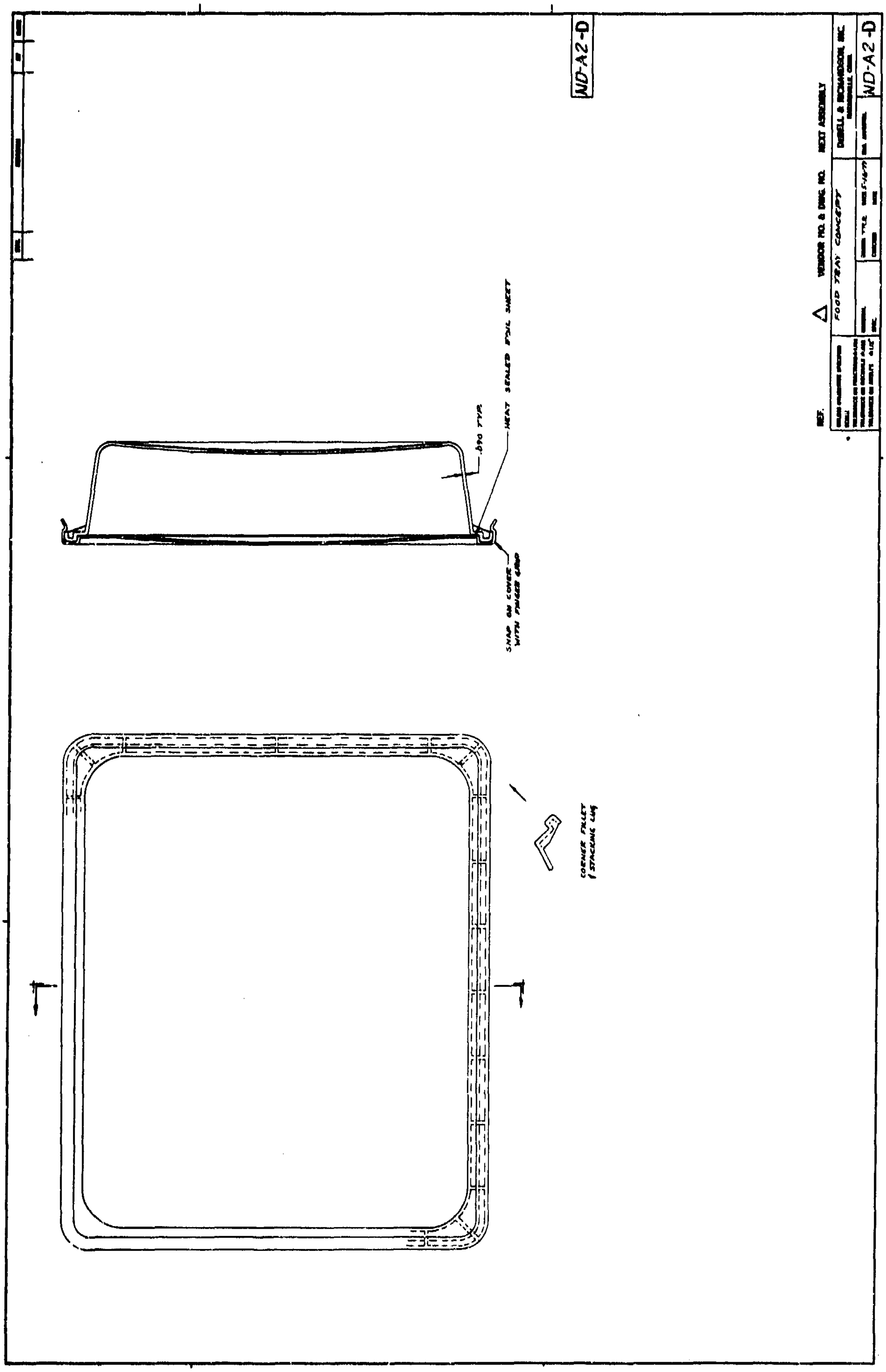
CLEARED UNDER §175.105 (ADHESIVES), §176.210 (DEFOAMING AGENTS USED IN THE MANUFACTURE OF PAPER AND PAPERBOARD) AND §178.3120 (ANIMAL GLUE) FOR USE AS THE FATTY TRIGLYCERIDE OR THE FATTY ACID, ALCOHOL, OR DIMER DERIVATIVE FOR PREVENTION OR CONTROL OF FOAM FORMATION.

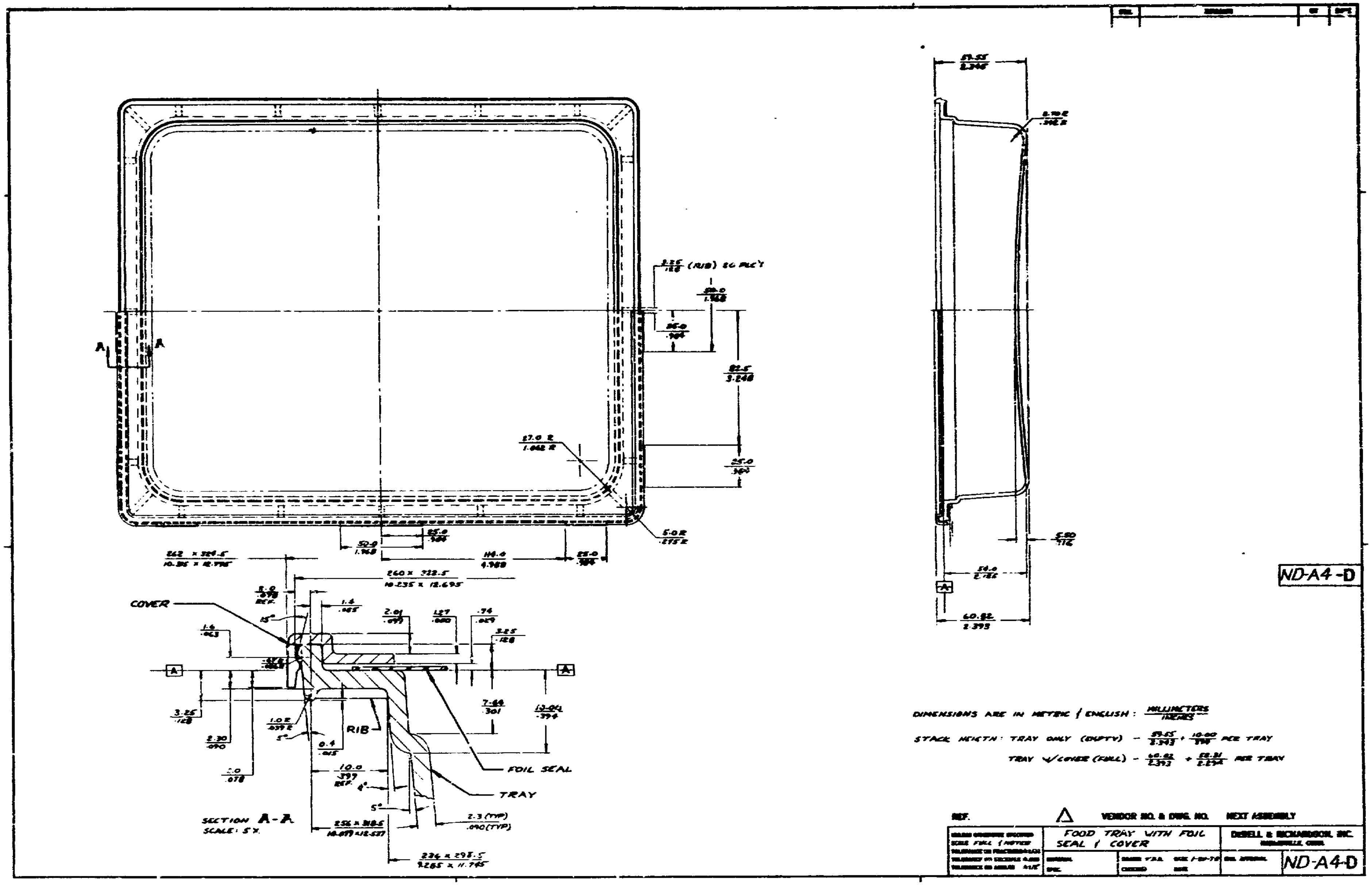
APPENDIX B

The following drawings are part of this report.

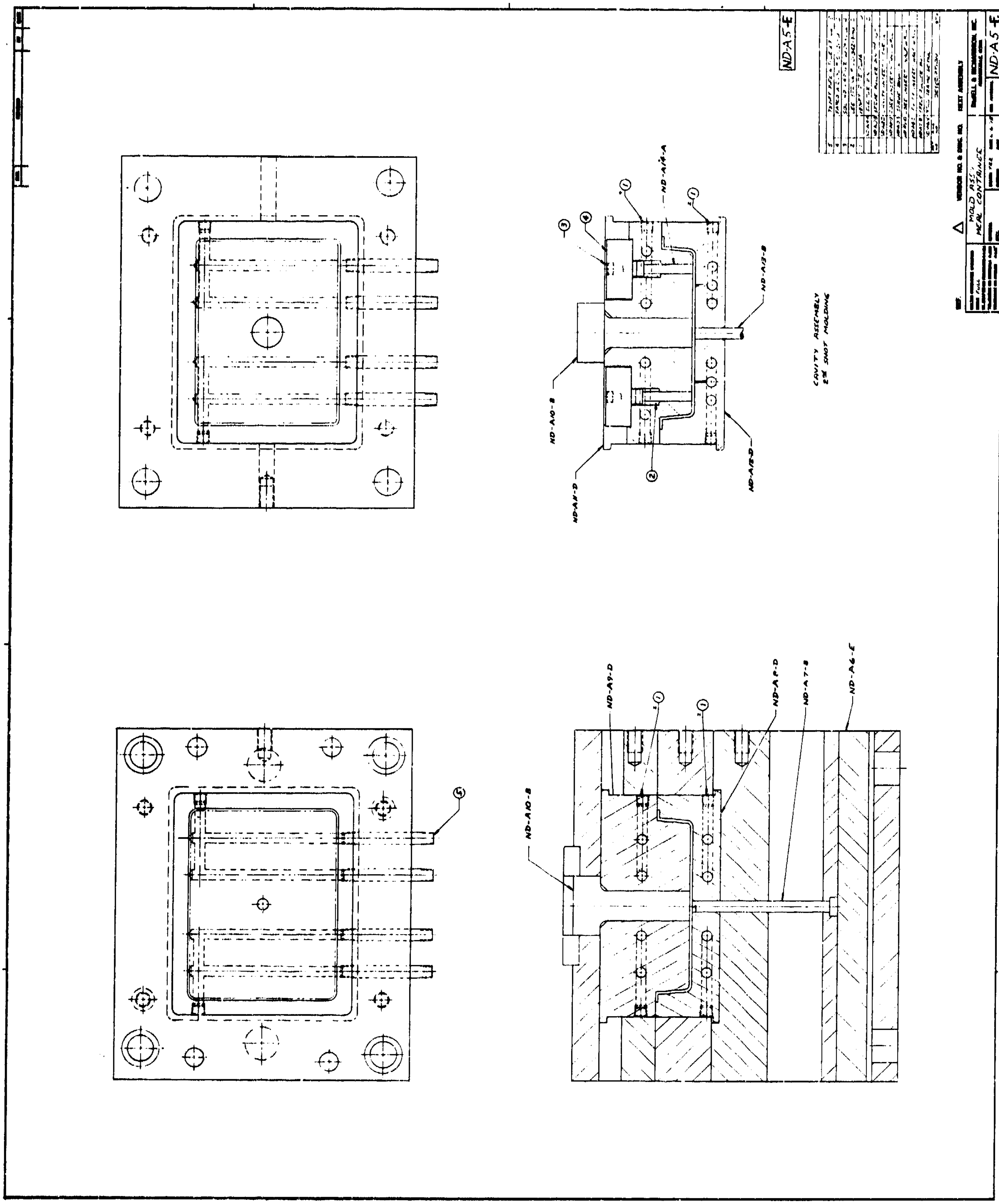
ND–A1–D	Food Tray Concept
ND–A2–D	Food Tray Concept
ND–A4–D	Food Tray with Foil Seal and Cover
ND–A5–E	Mold Assembly Meal Container
ND–A6–E	Mold Frame Detail
ND–A7–B	Sprue Puller Pin
ND–A8–D	Cavity Insert – Half Wall
ND–A9–D	Core Insert – Half Wall
ND–A10–B	Sprue Bushing
ND–A11–D	Core Insert – Full Wall
ND–A12–D1	Cavity Insert – Shrink
ND–A13–B	Sprue Puller – 2d Shot
ND–A14–A	Ejector Pin
ND–A15–D	Die Plate – Upper Heat Sealer
ND–A16–D	Support Plate Heat Sealer


ND-A1-D
FOOD TRAY CONCEPT
VENDOR NO. & DWG. NO.
NEXT ASSEMBLY
REF.
SECTION B-B
SECTION A-A
40.6 R-REF.
.090 TYP
69.7 R-REF.
CORNER FILLET & STACKING LUG
SNAP ON COVER
SNAP ON COVER WITH FINGER GRIP

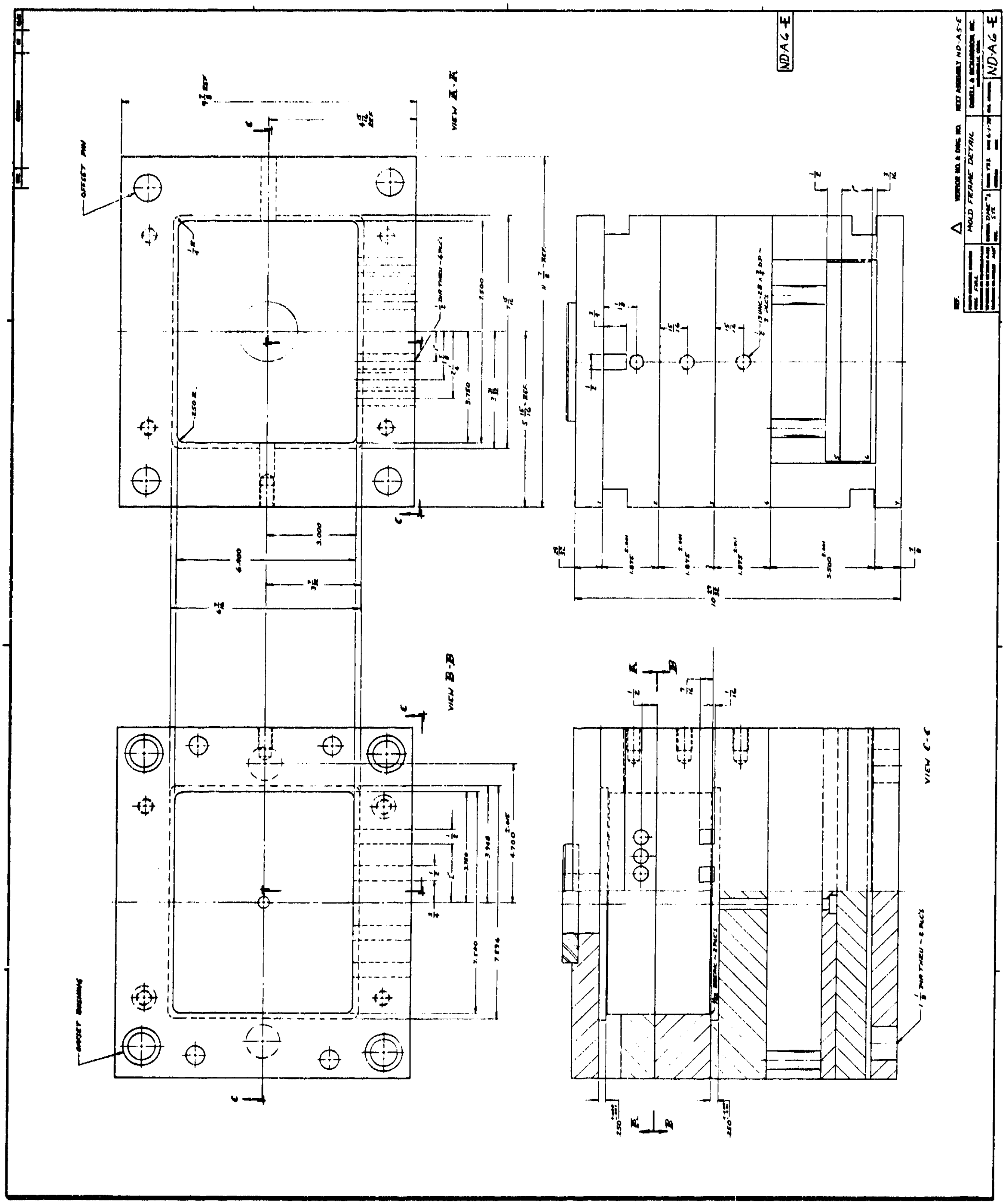

WD-A2-D
.090 TYP.
HEAT SEALED FOIL SHEET
SNAP ON COVER WITH FINGER GRIP
CORNER FILLET & STACKING LUG
VENDOR NO. & DWG NO.
NEXT ASSEMBLY
FOOD TRAY CONCEPT
WD-A2-D



ND-A4-D
COVER
RIB
FOIL SEAL
TRAY
SECTION A-A
SCALE: 5X
DIMENSIONS ARE IN METRIC / ENGLISH : MILLIMETERS / INCHES
STACK HEIGHT: TRAY ONLY (EMPTY)
TRAY W/COVER (FULL)
PER TRAY
REF.
VENDOR NO. & DWG. NO.
NEXT ASSEMBLY
FOOD TRAY WITH FOIL SEAL / COVER
DeBELL & RICHARDSON, INC.
ND-A4-D



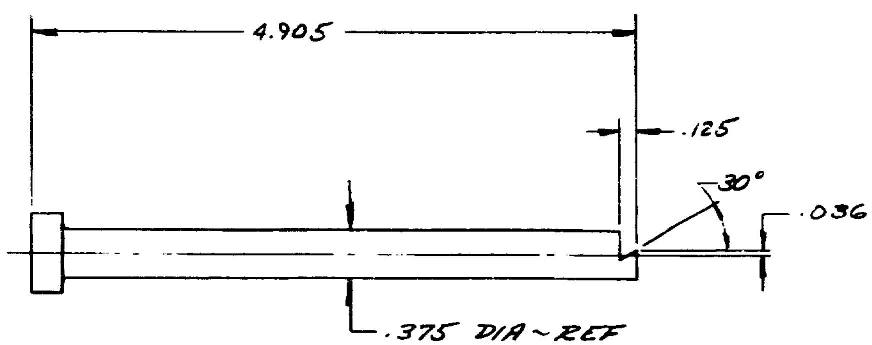
ND-A5-E
MOLD ASSY
MEAL CONTAINER
CAVITY ASSEMBLY
ND-A10-B
ND-A13-B
ND-A9-D
ND-A8-D
ND-A7-B
ND-A6-E



VIEW A-A
VIEW B-B
VIEW C-C
OFFSET PIN
OFFSET BUSHING
MOLD FRAME DETAIL
ND-AG-E

SYM.	REVISION	BY	DATE

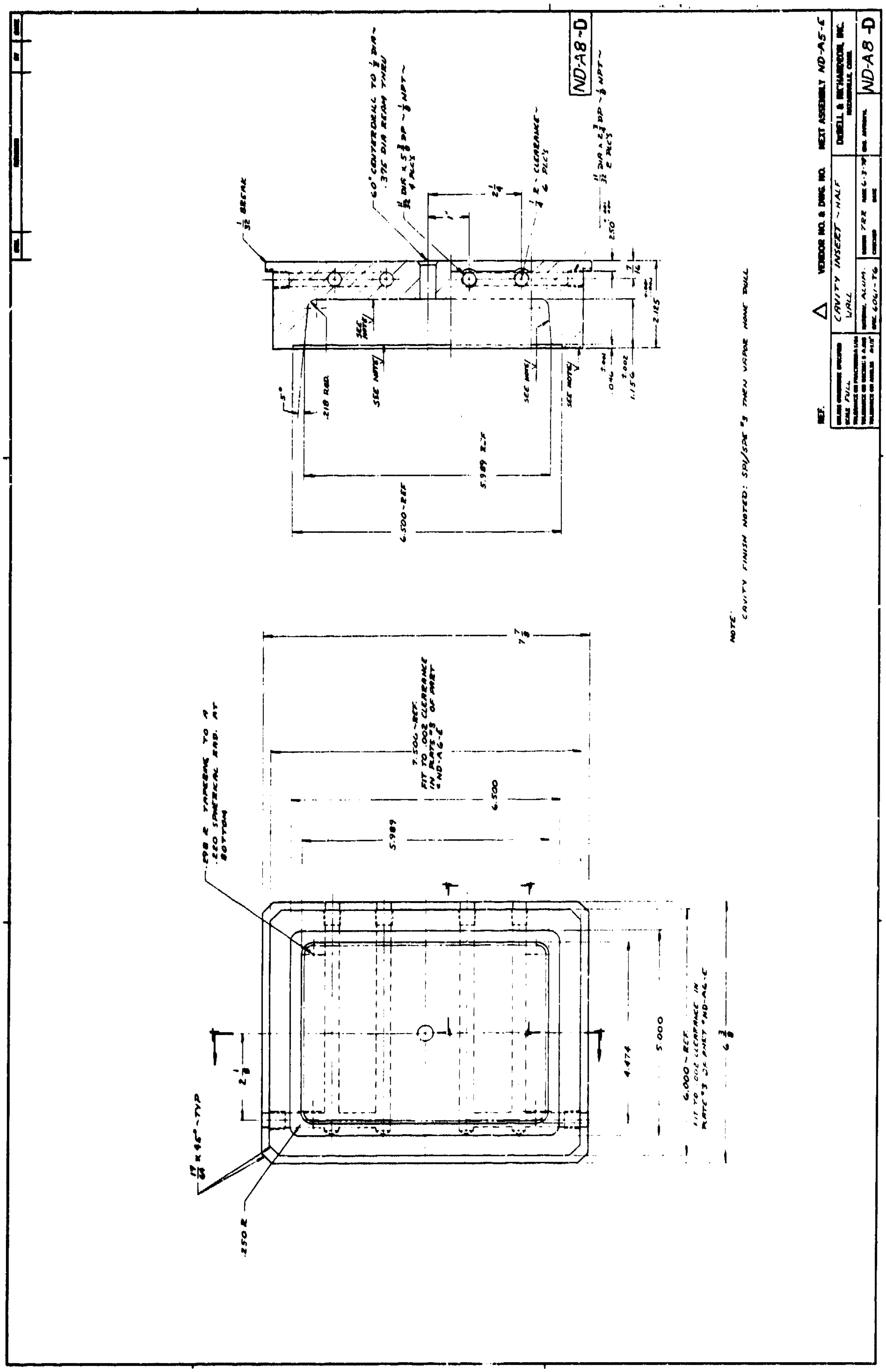
ND-A7 -B

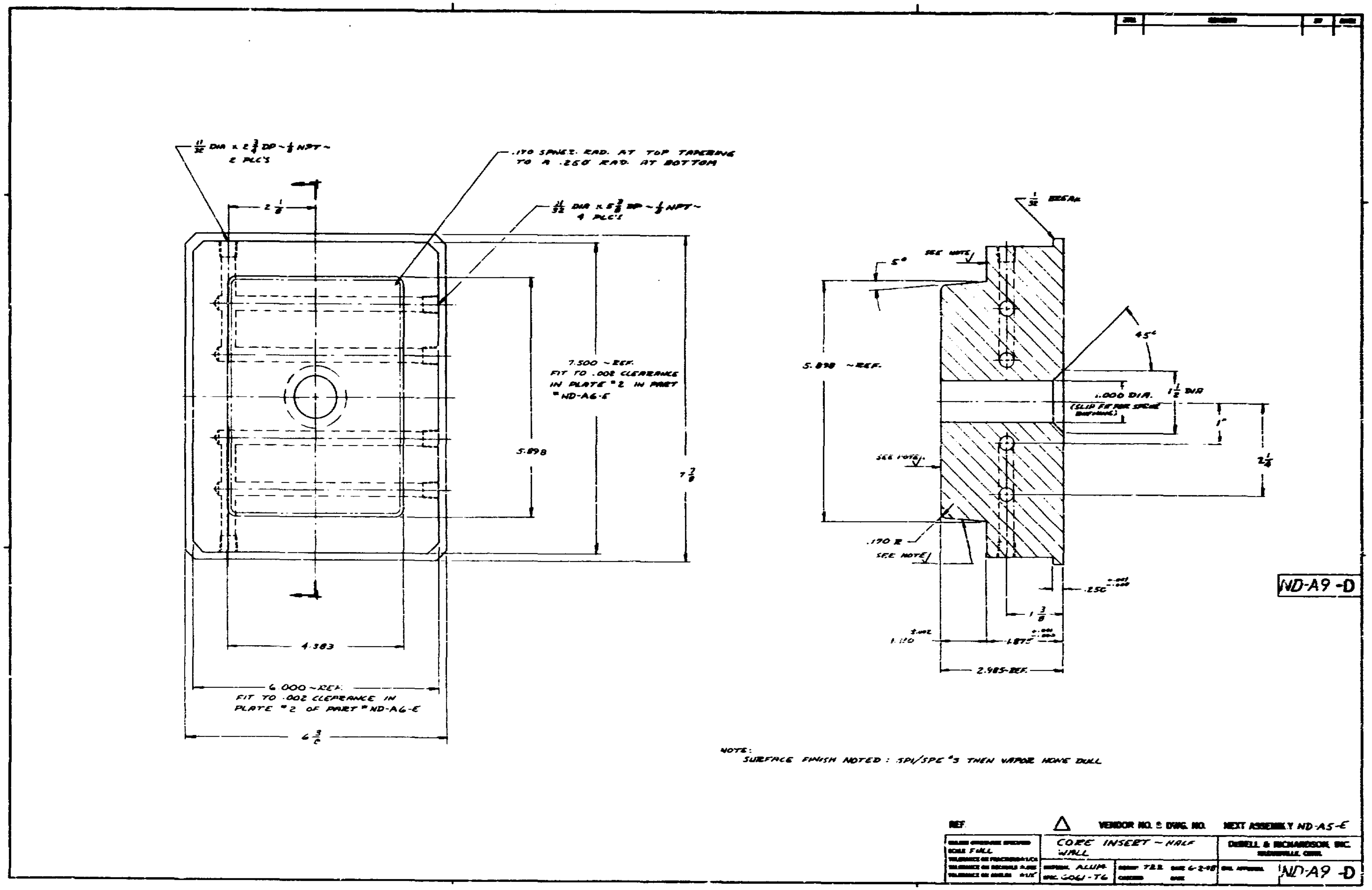


MAKE FROM DME SPRUE PULLER PIN # 7213

VENDOR NO. & DWG. NO. NEXT ASSEMBLY ND-A5-E

UNLESS OTHERWISE SPECIFIED SCALE FULL TOLERANCE ON FRACTIONS ±1/64 TOLERANCE ON DECIMALS ±.005 TOLERANCE ON ANGLES ±1/2°	SPRUE PULLER PIN MATERIAL AS NOTED SPEC.	DRAWN 722 DATE 6-5-78 CHECKED DATE	SPRINGBORN LABORATORIES, INC. ENFIELD, CONN. 06082 ENG. APPROVAL ND-A7 -B

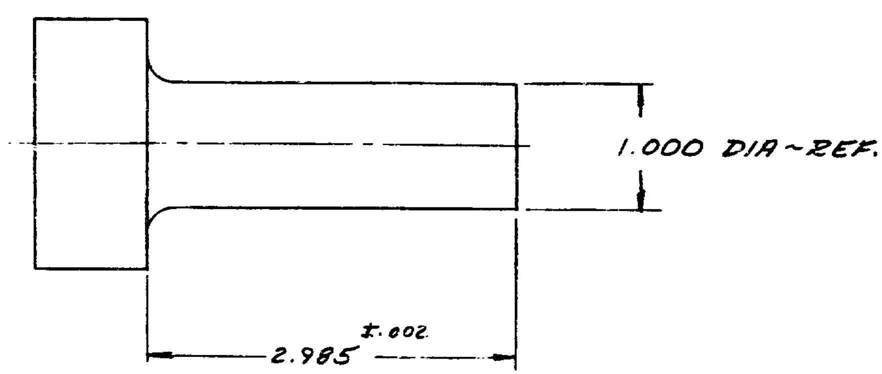

ND-A8-D
CAVITY INSERT ~ HALF
WALL
DESELL & RICHARDSON, INC.
VENDOR NO. & DWG. NO.
NEXT ASSEMBLY ND-A5-E
NOTE:
CAVITY FINISH NOTED: SPI/SPE #3 THEN VAPOR HONE DULL
60° CENTERDRILL TO 1/2 DIA ~ .375 DIA REAM THRU
1/32 BREAK
.218 RAD.
SEE NOTE
5.989 REF
6.500~REF
2.125
1.156
7.500~REF
FIT TO .002 CLEARANCE IN PLATE #3 OF PART # ND-A6-E
6.500
5.989
.298 R TAPERING TO A .220 SPHERICAL RAD. AT BOTTOM
.250 R
4.474
5.000
6.000~REF



11/32 DIA x 2 3/8 DP ~ 1/8 NPT ~ 2 PLC'S
.170 SPHER. RAD. AT TOP TAPERING TO A .250 RAD. AT BOTTOM
11/32 DIA x 2 3/8 DP ~ 1/8 NPT ~ 4 PLC'S
2 1/8
7.500 ~ REF.
FIT TO .002 CLEARANCE IN PLATE #2 IN PART #ND-A6-E
5.898
7 7/8
4.383
6.000 ~ REF.
FIT TO .002 CLEARANCE IN PLATE #2 OF PART #ND-A6-E
6 3/8
1/32 BREAK
SEE NOTE
5°
45°
5.898 ~ REF.
1.000 DIA.
1 1/2 DIA
(SLIP FIT FOR SPRUE BUSHING)
1"
2 1/4
SEE NOTE
.170 R
SEE NOTE
.250
1 3/8
1.110
1.875
2.985-REF.
NOTE:
SURFACE FINISH NOTED : SPI/SPE #3 THEN VAPOR HONE DULL
ND-A9-D
REF.
VENDOR NO. & DWG. NO.
NEXT ASSEMBLY ND-A5-E
SCALE FULL
CORE INSERT ~ HALF WALL
DeBELL & RICHARDSON, INC.
ALUM.
6061-T6
ND-A9-D

ND-A10-B

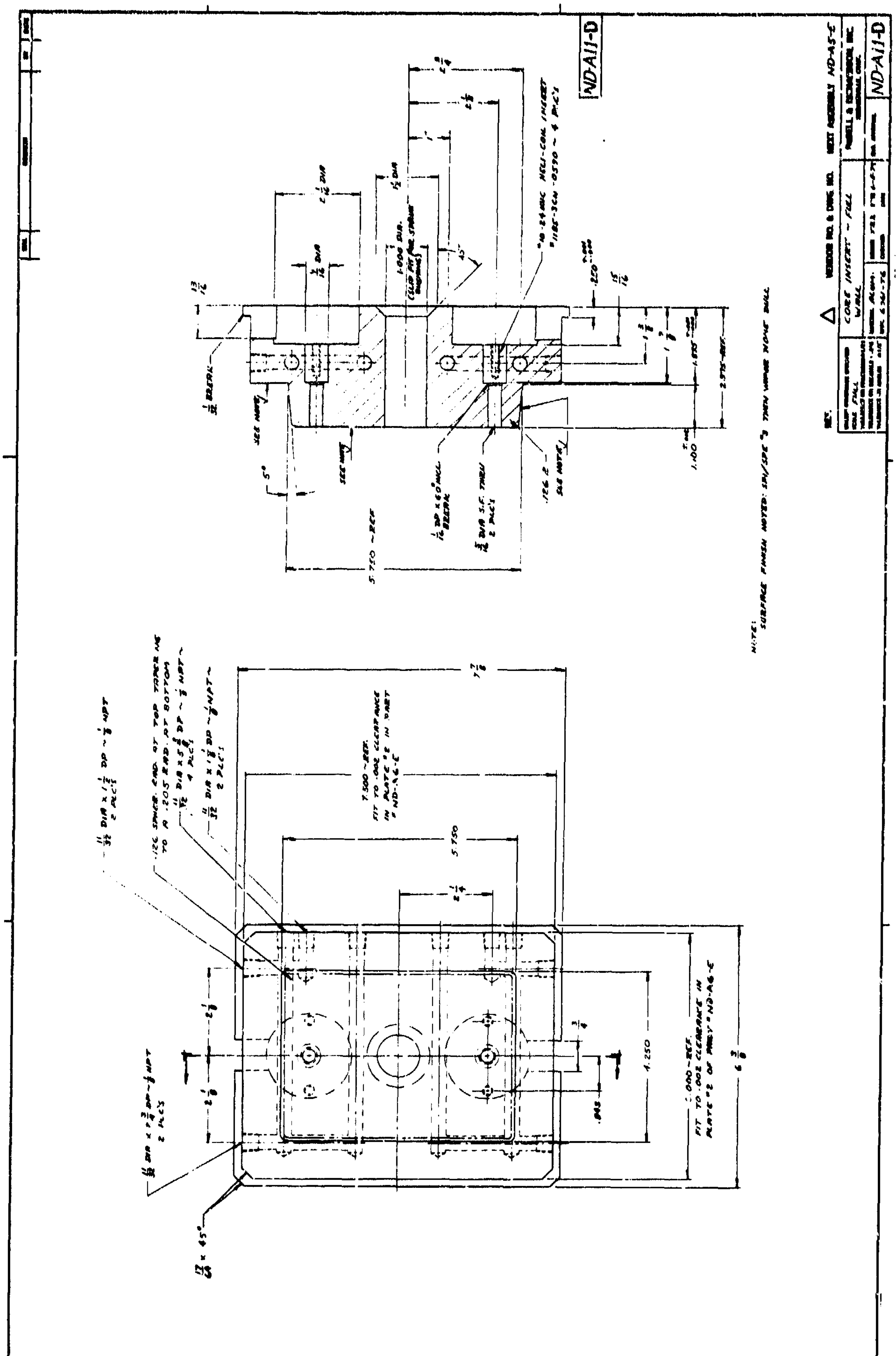
SYM.	REVISION	BY	DATE

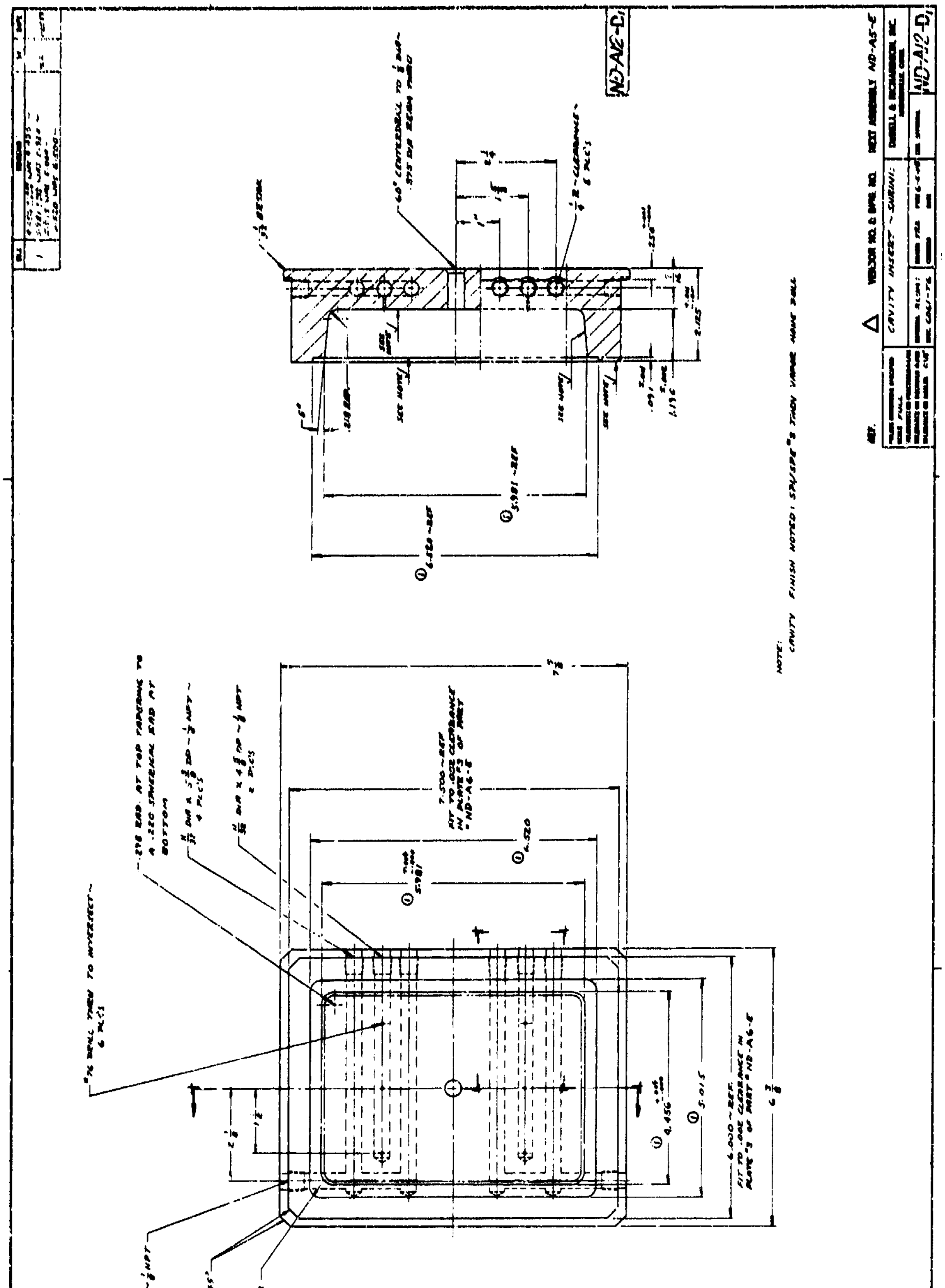


MAKE FROM DME SPRUE BUSHING #B-6605
1/2 SPHER. RAD. "C" = 7/32 DIA

△ VENDOR NO. & DWG. NO. NEXT ASSEMBLY ND-A5-E

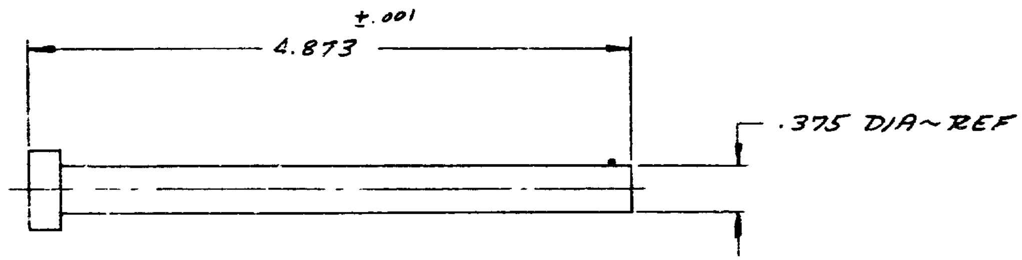
UNLESS OTHERWISE SPECIFIED SCALE FULL TOLERANCE ON FRACTIONS ±1/64 TOLERANCE ON DECIMALS ±.005 TOLERANCE ON ANGLES ±1/2°	SPRUE BUSHING MATERIAL AS NOTED SPEC.	DRAWN TZR DATE 6-5-78 CHECKED DATE	SPRINGBORN LABORATORIES, INC. ENG. APPROVAL ND-A10-B


ND-A11-D
CORE INSERT ~ FULL WALL
VENDOR NO. & DWG. NO.
NEXT ASSEMBLY ND-A5-E
NOTE:
SURFACE FINISH NOTED: SPI/SPE #3 THEN VAPOR HONE DULL
5.750 ~ REF
4.250
5.750
7.500 ~ REF.
FIT TO .002 CLEARANCE IN PLATE #2 IN PART # ND-A6-E
2.575 ~ REF.
1.00
1.000 DIA.
45°
5°
SEE NOTE


VENDOR NO. & DWG. NO.
NEXT ASSEMBLY ND-A5-E
CAVITY INSERT ~ SHRINK
ND-A12-D1
7.500 ~ REF
6.000 ~ REF
6 3/8
60° CENTERDRILL TO 1/2 DIA ~ .375 DIA REAM THRU
NOTE:
SEE NOTE

ND-A13-B

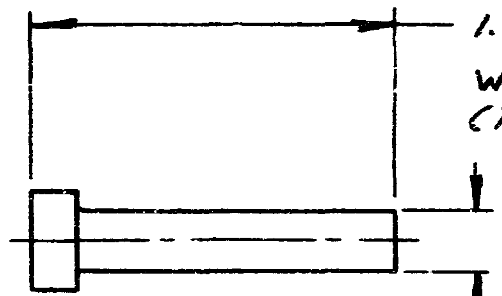
STM.	REVISION	BY	DATE



MAKE FROM DME SPRUE PULLER PIN # 7213

VENDOR NO. & DWG. NO. NEXT ASSEMBLY ND-A5-E

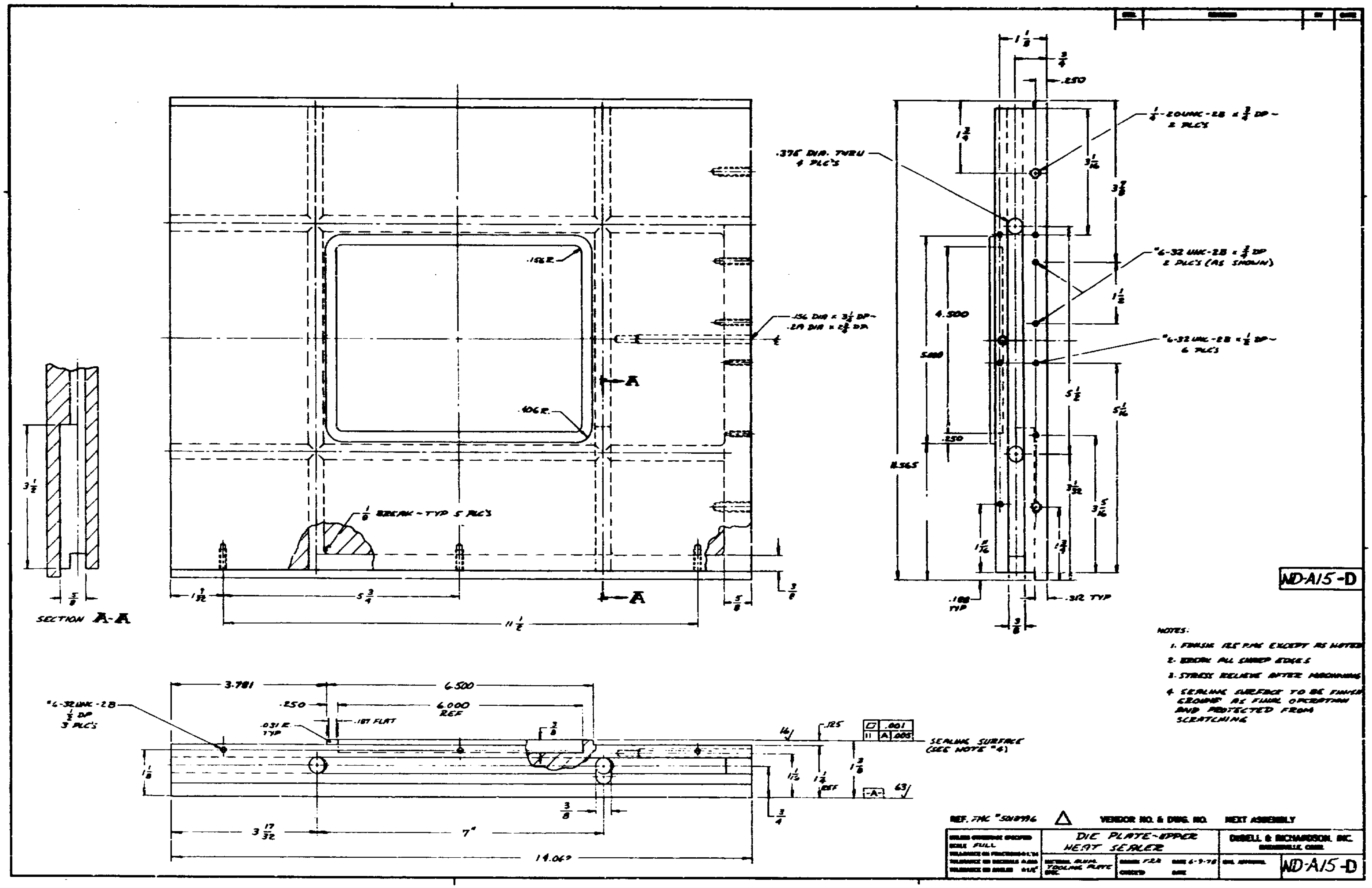
UNLESS OTHERWISE SPECIFIED SCALE FULL TOLERANCE ON FRACTIONS ±1/64 TOLERANCE ON DECIMALS ±.005 TOLERANCE ON ANGLES ±1/2°	SPRUE PULLER ~ 2nd SHOT		SPRINGBORN LABORATORIES, INC. ENFIELD, CONN. 06082
	MATERIAL AS NOTED SPEC.	DRAWN TRR DATE 6-5-73 CHECKED DATE	ENG. APPROVAL ND-A13-B

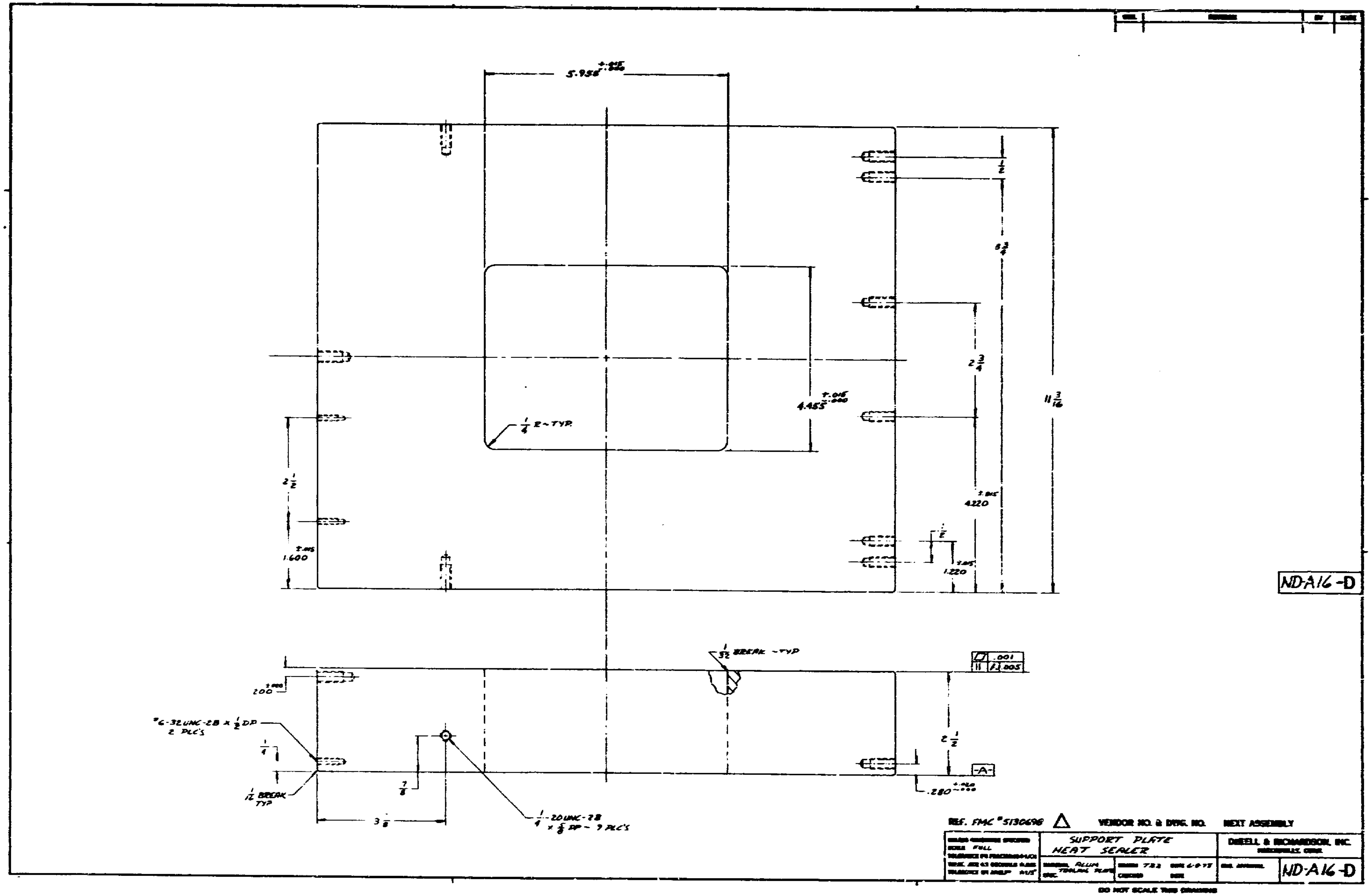


MAKE FROM DME EJECTOR PIN #EX-21 M-4

NEXT ASS'Y: ND-A5-E

UNLESS OTHERWISE SPECIFIED SCALE FULL TOLERANCE ON FRACTIONS ±1/64	EJECTOR PIN		DeBELL & RICHARDSON, INC. HAZARDVILLE, CONN.	
TOLERANCE ON DECIMALS ±.005 TOLERANCE ON ANGLES ±1/2°	MATERIAL AS NOTED SPEC.	DRAWN JRR DATE 6-6-78 CHECKED DATE	PROJECT NO. APPROVED	ND-A14-A


SECTION A-A
NOTES:
1. FINISH 125 RMS EXCEPT AS NOTED
2. BREAK ALL SHARP EDGES
3. STRESS RELIEVE AFTER MACHINING
4. SEALING SURFACE TO BE FINISH GROUND AS FINAL OPERATION AND PROTECTED FROM SCRATCHING
SEALING SURFACE (SEE NOTE #4)
.375 DIA. THRU 4 PLC'S
#6-32 UNC-2B x 1/2 DP 6 PLC'S
#6-32 UNC-2B x 3/4 DP 2 PLC'S (AS SHOWN)
1/4-20UNC-2B x 3/4 DP 2 PLC'S
1/8 BREAK-TYP 5 PLC'S
ND-A15-D
REF. FMC #SN8996
VENDOR NO. & DWG. NO.
NEXT ASSEMBLY
DIE PLATE-UPPER HEAT SEALER
DOBELL & RICHARDSON, INC.
SCALE FULL
ND-A15-D


ND-A16-D
5.958
4.465
1/4 R ~ TYP.
11 3/16
8 3/4
2 3/4
4.220
1.220
1/2
2 1/2
1.600
1/32 BREAK ~TYP
.001
.005
-A-
.200
#6-32UNC-2B x 1/2 DP
2 PLC'S
1/16 BREAK
TYP
7/8
3 1/8
1/4-20UNC-2B x 5/8 DP ~ 7 PLC'S
2 1/2
.280
REF. FMC # 5130690
VENDOR NO. & DWG. NO.
NEXT ASSEMBLY
SUPPORT PLATE
HEAT SEALER
DUELL & RICHARDSON, INC.
SCALE FULL
ND-A16-D
DO NOT SCALE THIS DRAWING

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